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REPROCESSING OF SINGLE-USE MEDICAL DEVICES

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS UNITED STATES SENATE

ONE HUNDRED SIXTH CONGRESS

SECOND SESSION

ON

EXAMINING THE SAFETY AND EFFECTIVENESS OF CERTAIN MEDICAL DEVICES, FOCUSING ON THE PRACTICE OF REPROCESSING AND REUSING CERTAIN MEDICAL DEVICES THAT WERE DESIGNED, MANUFACTURED, AND APPROVED BY FDA FOR USE IN A SINGLE PATIENT, DURING A SINGLE PROCEDURE

JUNE 27, 2000

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REPROCESSING OF SINGLE-USE MEDICAL DEVICES

TUESDAY, JUNE 27, 2000

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS,
Washington, DC.

The committee met, pursuant to notice, at 10:05 a.m., in room SD–430, Dirksen Senate Office Building, Hon. James Jeffords, chairman of the committee, presiding.

Present: Senators Jeffords, Frist, Collins, Kennedy, Dodd, and Reed.

Also Present: Senator Durbin.

OPENING STATEMENT OF SENATOR JEFFORDS

The CHAIRMAN. Good morning. The Committee on Health, Education, Labor, and Pensions will come to order. Welcome to the committee's hearing, "Reprocessing of Single-Use Medical Devices." I would like to extend a special welcome to our colleagues, Senator Durbin, who will be participating in the hearing a little later, and Representative Eshoo, who will be addressing the committee in a few minutes.

The American public relies on the Food and Drug Administration, FDA, to ensure that the medical devices used by doctors are safe and effective. Over the past several years, legitimate concern has been raised regarding the practice of reprocessing and reusing certain medical devices that were designed, manufactured, and approved by FDA for use in a single patient, during a single procedure. Some have argued that, in some instances, reprocessing can be a safe means to achieve financial savings in the health care system, while others have argued that the practice lacks proper oversight by FDA and presents an unreasonable risk to patient health.

Last year, I was joined by a number of my colleagues from this committee in requesting the General Accounting Office, GAO, to initiate a comprehensive evaluation of this practice in the United States, so that we could put this practice into proper perspective. Senator Durbin also requested a study, and GAO agreed to answer both requests with the report that we will hear about today.

We asked the GAO to look into a number of aspects of this practice, including how widespread the practice is; the economic impact; the role of the FDA; and, most importantly, what evidence can be found regarding the threat to public health associated with the practice of reprocessed, single-use devices.

The report that GAO will present today is largely inconclusive, but I think it raises questions about the regulatory process and the lack of information on the process and the practice. I hope that by the conclusion of today's hearing, we will have a better sense of what questions are left unanswered and what Congress and FDA can do to answer these questions; but whatever the questions and whatever the conclusion, the one question that must remain paramount is what course of action is in the best interest of these patients? I look forward to today's testimony and to constructive interaction with our witnesses as we all try to get to the goal that we share: protecting patient safety.

On our first panel this morning, we are glad to welcome Representative Anna Eshoo of California. Congresswoman Eshoo, the committee is very pleased to welcome you here today. Please proceed.

STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. ESHOO. Thank you and good morning to you, senator. I appreciate the invitation to come over and to testify on this important issue and to all the rest of the members of this distinguished committee who are not here yet this morning. This is something that I know that you have pursued, as other members of this committee have, and I am pleased to be here.

I have much to say on the issue, but in the interest of brevity, I have condensed my oral statement and I ask that my full written statement be made part of the record.

The CHAIRMAN. It will be.

Ms. ESHOO. Thank you. It is estimated that as many as one in every three hospitals in our country are reusing medical devices on patients without their knowledge or consent. Reuse of delicate medical devices like balloon catheters and biopsy forceps have been linked to patient injuries and infections in our country. A 50-year-old woman needed surgery when two reprocessed catheters broke during a brain scan. Premature babies have suffered infections from unsterile sutures. As recently as February of this year, an elderly woman in Florida suffered significant complications when a reprocessed forceps device failed during a routine procedure to remove kidney stones.

Reprocessors tell us that reprocessing is perfectly safe. They will testify today that the GAO report found little evidence that reusing devices intended for single use only causes infection or injury. What we are not told, however, is that we have very little information about the scope of patient injuries because we do not require patient consent and hospitals do not have to track whether a reused device was involved in an adverse event. We cannot say definitely whether reprocessing is safe or not because there has been virtually no oversight of the practice over the last 20 years.

FDA clearly has the authority to enforce premarket safety and effectiveness requirements, yet in my view it has essentially looked the other way. There is nothing on the books that prevents hospitals from using a reprocessed device on a patient without their knowledge or consent and nothing is required to prove that the device is safe and effective and nothing prevents a hospital from

charging the patient and the Federal Government through Medicare for a new device when a second one is used.

When we buy a part for our automobile, the mechanic is required to tell us if the part is new or rebuilt and we are charged accordingly. I think that our laws can do a much better job or they do a much better job of covering car parts than protecting patients.

Last November, I introduced the Reprocessed Single Use Medical Device Patient Safety Act—that is H.R. 3148—because I saw a failure on the part of our government and the FDA to address the safety of reprocessing in a very meaningful way. The bill ensures the protection of patients by requiring reprocessed medical devices to meet the same safety and effectiveness standards that new products must meet.

H.R. 3148 will also increase awareness about reprocessed devices by requiring a patient's informed consent before a single use medical device may be used on them and also requiring hospitals to monitor and report injuries or infections that occur as a result.

When FDA approves the device for single use only, that is exactly what it means, that the data submitted by the manufacturer has shown that this device can be safely used one time only. Thus, a company that reprocesses the device and reuses it multiple times should be required to inform the patient that they are not getting what the label advertises. These labels should mean exactly what they say: single use means single use. A reprocessed single-use device is a multiple use device and the label should say so. If not, patients, in my view, should be informed and their consent requested.

I am encouraged that FDA has finally developed a proposed policy requiring premarket approval for all reprocessed devices. However, I remain concerned that they may not follow through with this approach. I understand that in recent speeches that FDA officials have indicated that the agency will not require PMAs or 510(k)s to demonstrate that the devices can be safely and effectively reprocessed multiple times.

If, in fact, there is backtracking, I would call that into question. I am concerned that it is yet another indication that the agency will not bring about true enforcement of the data requirements on reprocessors and I think that that is not good for patient care and quality care in our Nation.

The GAO report raises significant questions in my view about the safety of reprocessing and the need for meaningful oversight of the practice. One, without premarket approval, how do we ensure that all reprocessed devices undergo carefully controlled reprocessing? How do we determine which single-use devices can be reprocessed safely and which ones cannot? Should we leave it up to the very industry that obviously its bottom line is a profit, which we recognize? We respect that in our country, but I do not think that that is good enough. Without informed consent and tracking, how will we know when reprocessed devices have been used safely or not?

Mr. Chairman, I look forward to working with you. You have given great leadership on this issue with the rest of this distinguished committee to finding a thoughtful solution that will be effective for the American people and also that the industry, I might say, will be able to go out and be able to say with great confidence

that these devices by the very process of approval are safe for patients and the hospitals that use them across our Nation. So I thank you for this generous invitation to testify and I look forward to moving this legislation forward.

The CHAIRMAN. Well, thank you very much. You stated the problem very astutely and accurately, and we look forward to working with you. We have several witnesses this morning who will give us more information. And if the FDA adequately regulates this process so that safety is guaranteed, do you think informed consent is still necessary?

Ms. ESHOO. I think it is a very important point to raise and I raised it in the legislation because most frankly there is not anything on the books. I am pleased that the FDA—that there is some movement. But I think if there is not a process by which the patient, the consumer, so to speak, is guaranteed that they are safe, then I think the consent has already been given by the government, so to speak, that they can stand behind the product. But there is not anything today, and that is very disturbing. It is very disturbing, and there is an irony that these devices are called single-only use, but it does not live up to the advertising.

So I think that we have a ways to go on this, and I know that people, the industry, do not like the informed consent. I do not like to alarm people and I think that anyone that goes into the hospital, whatever it is, their anxiety level is probably raised. Whether someone is going to wave a label before then is questionable and I think that to layer on something else in terms of their anxiety to say that what is going to be used on them is questionable do they want it used or not? But the fact of the matter is is that today these devices are being used. They do not know the status of them, and I think that as legislators, we are casting the light on this and that we can do much, much better in this country. Certainly the incidences that have occurred are serious enough to warrant our stepping in legislatively.

So I think that if we can cover all the other bases, that maybe informed consent will go away, but I think that we still have a ways to go before we achieve that.

The CHAIRMAN. Thank you very much.

Ms. ESHOO. Thank you.

The CHAIRMAN. A pleasure having you with us, and we look forward to working with you.

[The prepared statement of Ms. Eshoo follows:]

PREPARED STATEMENT OF REPRESENTATIVE ESHOO

Thank you, Mr. Chairman and Senator Kennedy for holding today's hearing on the very important issue of reuse of single-use medical devices.

I come to this issue from the perspective of both a legislator and a consumer. As a legislator, I have grave concerns about the FDA's failure to date to enforce meaningful safety and effectiveness requirements for reprocessed single-use devices. I question the logic of requiring new medical devices to meet basic patient safety standards yet failing to require the same standards for reprocessed and reused ones.

As a consumer, I'm horrified to know that complex, delicate devices, such as cardiac balloon catheters and biopsy forceps, are being cleaned and used again on different patients with little proof that it can be done safely.

Reuse of delicate medical devices, like balloon catheters and biopsy forceps, has been linked to patient infection and injury. As recently as February of this year, an elderly woman in Florida suffered significant complications when a reprocessed forceps device failed during a routine procedure to remove kidney stones. During the

procedure, the grasping forceps broke off and lodged in the patient's ureter, cutting off access to the bladder. The attending physician was forced to conduct emergency surgery to remove the failed device and reattach the patient's bladder. The patient has since suffered significant complications and has had to undergo further surgical procedures to remove unhealed scar tissue in her bladder.

The patient's daughter, Ms. Georgia Abernathy, suspected that the grasping forceps used on her mother may have been reprocessed and that repeated sterilizing and reuse fatigued the device to the point of failure. It's only because Ms. Abernathy, employed by a manufacturer of single-use devices, is aware of the dangers of reprocessing, that she investigated. For more than two weeks, Ms. Abernathy questioned hospital personnel about whether the hospital uses reprocessed grasping forceps. Finally, they admitted that they do use reprocessed single-use devices on patients without their knowledge and that the device that was used on Ms. Abernathy's mother was, in fact, reprocessed.

If not for Ms. Abernathy's tenacity and familiarity with the risks of infection and device failure that accompany reprocessing, she would never have known that a reprocessed device was involved in her mother's injury. Most patients are unaware that reprocessing even occurs. Most situations like the one experienced by Ms. Abernathy's mother are neither investigated nor reported.

The reprocessors here today will tell you that reprocessing is perfectly safe. They will say that the GAO report found little evidence that reprocessing and reusing devices intended for single use only cause infection or injury. What they won't tell you however, is that we have very little information about the scope of patient injuries. Of course there's little evidence. We don't require patient consent and hospitals don't have to track whether a reused device was involved in an adverse event. We can't say definitively whether reprocessing is safe or not because there's been virtually no oversight of the practice for the past 20 years.

We don't even know the extent to which reprocessing occurs. It's estimated that as many as one in every three hospitals are reusing single-use devices and none are required to report whether a reprocessed device was involved in an adverse event. FDA doesn't even know of all the reprocessors that exist. According to the GAO report, FDA suspects there are third-party reprocessors that have never even registered with them.

FDA clearly has the authority to enforce safety and effectiveness standards, yet it has looked the other way, allowing this practice to go on with very little oversight. In fact, in a letter dated July 9, 1999, FDA admitted that reprocessing a medical device constitutes re-manufacturing a device and, as such, is subject to the same pre-market safety and effectiveness standards as original equipment. Yet, to date FDA has chosen not to enforce these standards.

Today, there is nothing on the books that prevents hospitals from using a reprocessed device on a patient without their knowledge or consent. Nothing is required to prove that the device is safe and effective. And nothing prevents a hospital from charging the patient and the Federal government through Medicare for a new device when a secondhand one is used. When we buy a part for our car, the mechanic is required to tell us if the part is new or rebuilt and we are charged accordingly. Why is it that our laws are doing a better job covering car parts than they do protecting patients?

Until recently, FDA's primary reason for not enforcing these standards was the increased regulatory burden. I find this an irresponsible and fully unacceptable failure on the part of FDA to ensure patient safety. I understand that FDA has a lot on its plate. However, patient safety must always come first.

I introduced the Reprocessed Single-Use Medical Device Patient Safety Act (HR 3148) because I saw a real failure on the part of FDA to address the safety of reprocessing in a meaningful way. My bill ensures the protection of patients by requiring reprocessed medical devices to meet the same safety and effectiveness standards that new products must meet. HR 3148 will also increase awareness about reprocessed devices by requiring a patient's informed consent before a single-use medical device may be used on them and requiring hospitals to monitor and report injuries or infections that occur as a result.

When FDA approves a device for single-use only, that's exactly what it means—that the data submitted by the manufacturer has shown that this device can be safely used once. Thus, a company that reprocesses the device and reuses it multiple times should be required to inform the patient that they aren't getting what the label advertises—a single-use, disposable device.

These labels should mean exactly what they say. Single-use means you can only use it once. A reprocessed single-use device is a multiple use device and the label should say so. If not, patients should be told and their consent obtained.

I'm encouraged that FDA has finally developed a proposed policy with regard to reprocessing and reuse. However, I'm concerned that their willingness to properly regulate the industry continues to evolve at an erratic pace. In their proposed enforcement guidance, FDA stated that while all reprocessed single use devices are subject to the same pre-market safety and effectiveness requirements as new devices, FDA wouldn't enforce these requirements unless the device was considered "high risk." Following numerous questions about the logic of requiring one to show whether reuse of a particular device poses a "high risk" to patients without the data, FDA suddenly changed its proposal to include all single-use devices—just in time for a Commerce Committee hearing.

FDA's new draft guidance states that they will require premarket approval for all reprocessed devices. However, I understand that in recent speeches, FDA officials have indicated that FDA will not require PMAs or 510(k)s to demonstrate that the devices can be safely and effectively reprocessed multiple times. This recent backtracking calls into question FDA's motivation to properly regulate reprocessing. I'm concerned that it's yet another indication that FDA plans to delay true enforcement of the data requirements on reprocessors for as long as possible.

I understand the fiscal constraints hospitals are under. Between managed health care and reduced Medicare reimbursements, hospitals feel intense pressure to cut costs wherever possible.

However, we can't continue putting patients at risk in order to save a few dollars. We must put patients before profits. The Reprocessed Single Use Medical Device Patient Safety Act is about putting patients first.

I look forward to working with you, Mr. Chairman, and with the rest of the distinguished Committee members to find a thoughtful solution to this problem. Thank you.

The CHAIRMAN. Our next witness will be Dr. David Feigal representing the U.S. Food and Drug Administration. Dr. Feigal received his M.D. from Stanford University Medical School and an M.P.H. from the University of California, Berkeley.

Dr. Feigal joined the Food and Drug Administration in 1992, heading the Division of Anti-Viral Drug Products, a position he held until 1997. In the fall of 1997, he moved to the Center for Biologics Evaluation and Research as the Medical Deputy Director. Dr. Feigal is currently the Director of the Center for Devices and Radiological Health, the center with regulatory responsibility over medical devices.

Dr. Feigal, we are pleased to have you with us, and if you would like to introduce the person with you, I would appreciate it.

Dr. FEIGAL. Actually I believe it is the witness after me.

The CHAIRMAN. Oh, okay. I will do that.

Dr. FEIGAL. OK. Good.

The CHAIRMAN. All right. Go right ahead. Just testing you to see how alert you were. [Laughter.]

Dr. FEIGAL. OK. Good. Yeah. Well, we are adding new staff all the time. I have to check. [Laughter.]

STATEMENTS OF DAVID W. FEIGAL, JR., M.D., M.P.H., DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION; ROCKVILLE, MD; AND JANET HEINRICH, DR.PH., R.N, ASSOCIATE DIRECTOR, HEALTH, EDUCATION AND HUMAN SERVICES DIVISION, GENERAL ACCOUNTING OFFICE, WASHINGTON, DC

Dr. FEIGAL. Well, Mr. Chairman, I am pleased to be here today to discuss our approach to the issue of reissuing medical devices labeled for single use. We value your interest and input as we move forward to change our regulatory approach. Our primary goal is to protect the public health by assuring that reprocessed single-use devices are safe, effective and well manufactured.

Let me say at the outset that I believe we have the regulatory tools to ensure that this happens. We are crafting a new strategy that will apply our existing regulations equally to the original manufacturer of a device and to those who reprocess it including commercial reprocessing firms at the hospitals. For example, reprocessors like original manufacturers will be required to meet our traceability regulations. A single-use device must be appropriately labeled, and with the requirement that original manufacturers and reprocessors meet the same regulatory standards, the difference in these devices will be the starting materials, not the end products.

I think this approach will give the public health protection we all desire. In February, we posted on our website two draft guidance documents that pertained to single-use devices. One described a proposed risk prioritization scheme and the other described our enforcement priorities. The public comment period for these documents closed on April 11 and in general the comments have been supportive of our decision to treat all reprocessors of single-use devices the same.

Some would like us to phase in hospital compliance more slowly. Others would have us step up the enforcement more quickly and still others have suggested that we could simplify the approach laid out for the way that we phase in the process.

By way of background, let me describe how reuse has grown over the years and why it poses a problem today that did not exist a few decades ago. The practice of reusing medical devices intended for only one use began in the hospitals in late 1970s. Prior to that time, most medical devices were considered to be reusable. Because most devices were made of glass, rubber or metal, early processing involved little more than wiping, dipping, soaking in disinfectant.

Things began to change as a result of market demand for disposable equipment and the development of new plastics. As a result, hospitals began to receive products labeled "single-use only" that were similar devices that had formerly been sold as reusable.

The practice of reprocessing single-use devices expanded when an increasing number of hospitals decided that reuse was a cost-saving measure, the advent of new methods of sterilization, and because of the concern about the medical waste generated by the use of disposable devices. The hospitals themselves started reprocessing more complex and delicate products such as balloon angioplasty catheters and other cardiovascular catheters. As reprocessing required more complicated decontamination and sterilization procedures, a new industry of third-party processors evolved in response to the needs of hospitals.

All of this has resulted in a heightened concern about the safety and effectiveness of reused single-use devices and about the equitable regulation of original equipment manufacturers and reprocessing firms.

Where does FDA stand on this issue? We have concluded that the practice of reuse does need additional attention and active oversight. We have come to this conclusion even though we do not have clear evidence that reprocessing single-use devices increases risk to patients. Patient injuries are not the only reason for our taking action. Even without documented injury, the law still requires that

we assure that reprocessed devices are safe, effective and manufactured properly.

I do not want to leave you the impression that we are coming new to this issue. We have been actively engaged in the reuse issue for some time and much more actively in the past year. We have held numerous meetings and conferences with industry, health professionals and consumers to determine the extent, magnitude and changing nature of this practice.

We have evaluated and conducted research to help develop a scientific basis for addressing the issue. We have inspected third-party reprocessors and, as a result, have issued ten warning letters for various violations. And we have investigated reports of patient injuries.

Let me describe what we are proposing to do in this area. Fundamentally, our strategy is based on the degree of risk posed by the device. There are several steps to developing this strategy to enforce our existing regulations. First, develop a list of commonly reused single-use devices. Second, develop a list of the factors to determine the degree of risk associated with reprocessing. The primary factors are the risk of infection and the risk of performance deterioration if a product is reused. Third, use this information to divide the list of commonly reprocessed single-use devices into three categories of risk: high, moderate, and low. And four, develop priorities for enforcement of regulatory requirements for hospitals and third-party processors based on the categories of risk.

I should mention that we are limiting our focus as we begin to third parties and to hospitals. For now, we are not including health care facilities in this strategy that are not hospitals. Since announcing this new strategy, we have made significant progress. As I mentioned, we posted the two companion draft guidances that set forth these factors, and specifically we intend to begin enforcing premarket notification application requirements within 6 months of issue of the final guidance if the reprocessed device is categorized as a high risk, 12 months if the device is moderate risk, and 18 months if the device is low risk.

In response to one of the questions raised by Representative Eshoo, we have not backed off or changed any of the standards that we have proposed to require 510(k)s and PMAs.

Mr. Chairman, let me close by saying that although we have no clear data to indicate that people are being harmed by the reuse of single-use devices, the results of our own research and the information provided by various stakeholders have convinced us that this growing practice needs closer scrutiny and oversight. We are committed to addressing reuse in an open and cooperative fashion with the industries involved, the health care community, the public, and, of course, Congress. We want a reasonable and fair-minded policy, but at the same time, we want to assure that when a single-use device is reused, it does not expose the patient to more risk than a brand new device would. Thank you for the opportunity to be here today. I will be happy to answer questions.

The CHAIRMAN. Well, thank you very much, doctor.

[The prepared statement of Dr. Feigal follows:]

PREPARED STATEMENT OF DAVID W. FEIGAL, M.D.

INTRODUCTION

Mr. Chairman, Members of the Committee, I am Dr. David Feigal, Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration (FDA or the Agency). I am very pleased to have the opportunity to be here today to discuss the Agency's approach to the issue of reuse of medical devices labeled for single-use. As you know, FDA has re-examined its policy on this issue. Our primary goal in doing so is to protect the public health by assuring that the practice of reprocessing and reusing single-use devices (SUDs) is safe and effective and based on good science. We value your interest and input as we move forward to implement our regulatory strategy.

The public expects and the law requires all medical devices to be safe, effective and manufactured in accordance with good manufacturing practices (GMPs). Let me say at the outset that I believe FDA does have the tools to ensure the safety, effectiveness, and manufacturing quality of reprocessed SUDs. We have been actively engaged in reuse issues for some time and our efforts have included research, outreach, inspections, and compliance investigations. We are currently in the midst of developing an approach that will apply existing regulations to original equipment manufacturers (OEMs), third parties, and hospitals in a similar manner to minimize risks associated with reprocessed SUDs.

We have held numerous meetings and conferences with industry, health professionals, and consumers over the past several years to determine the extent, magnitude and changing nature of the practice. We have evaluated and conducted research. We have inspected third-party reprocessors. We have investigated reports of patient injuries. We understand that economic pressures create incentives for hospitals to reuse devices labeled for single-use and we also know that changes in technology have resulted in more devices with features that may make reprocessing difficult or impossible. Despite a lack of clear data that directly link injuries to reuse, FDA has concluded that the practice of reprocessing SUDs merits increased regulatory oversight. We are concerned because we do not yet have enough information to be certain that reprocessed SUDs are being manufactured properly, and we recognize that our medical device problem reporting systems cannot adequately capture information about potential clinical problems related to reuse. Our plan is to phase-in additional oversight based on our assessment of current practice and potential risk.

In February, we posted two draft guidance documents that pertain to the reuse of SUDs. One described a proposed risk prioritization scheme for reprocessed SUDs. The other described the Agency's proposed priorities for enforcing various regulatory requirements based on the risk associated with a reprocessed SUD. The public comment period for these documents ended on April 11, 2000, and we are now completing our analysis of the feedback we have received. In general, the comments have been very supportive of the Agency's decision to treat all reprocessors of SUDs, whether third-party firms or hospitals, in a similar manner. Some commentors asked us to phase-in our increased oversight more slowly to give hospitals a chance to become familiar with FDA requirements. Other stakeholders believe FDA is not moving quickly enough to enforce its requirements. Many stakeholders suggested we simplify the approach we had set out in the draft guidances for enforcement priorities by matching our phased-in approach to the current classification system. Let me now provide some background on reuse to put FDA's current initiatives in perspective.

BACKGROUND

The History of Reprocessing and reuse of SUDs

The practice of reusing medical devices labeled, or otherwise intended, for only one use began in hospitals in the late 1970s. Prior to this time, most medical devices were considered to be "reusable." Because most reusable devices were fabricated from glass, rubber, or metal, early reprocessing of reusable products, such as probes and surgical instruments, involved a little more than hand wiping, dipping, and soaking in disinfection solutions. OEMs began to sell "single-use" medical devices as a result of market demand for disposable equipment, the development of new plastics, and the use of ethylene oxide sterilization. Hospitals began to see products labeled "single-use only" that were similar to devices that had been formerly distributed or continued to be distributed as "reusable."

The practice of reprocessing SUDs expanded when an increasing number of hospitals decided that reuse was a cost-saving measure and when they became concerned about the amount of medical waste generated by the use of disposable devices. Hospitals started reprocessing more complex products, such as balloon angioplasty and other cardiovascular catheters. Reprocessing of these devices re-

quired more complicated decontamination and sterilization procedures. As a result, an industry of third-party reprocessors evolved in response to the reprocessing needs of hospitals. Expanded use of third-party reprocessors and an increase in the types of SUDs subjected to reprocessing heightened concerns regarding both patient safety and a level playing field for OEMs and reprocessing firms.

The Scope of Reuse Today

The Agency has developed a list of frequently reprocessed SUDs, which includes devices that range from the technologically simple to the complex. Examples include:

- Surgical Saw Blades
- Surgical Drills
- Laparoscopy Scissors
- Orthodontic (metal) Braces
- Electrophysiology Catheters
- Electrosurgical Electrodes and Pencils
- Respiratory Therapy and Anesthesia Breathing Circuits
- Endotracheal Tubes
- Percutaneous Transluminal Coronary Angioplasty Catheters
- Biopsy Forceps

The list varies greatly in type of device, material, risk of use and severity of clinical conditions of typical use. Some products have features such as long narrow lumens, fragile plastic components, and/or unsealed electronic controls that make them very difficult to clean. Other products on the list, e.g., drill bits, are technologically less complex and are relatively easy to clean.

A common type of reuse in hospitals occurs when a sterile product, such as a suture, is opened during a medical procedure but not used. Typically, these are resterilized and re-packaged at the hospital. OEM's often provide instructions for hospitals to do so or replace the opened product with new stock. The Agency has published applicable guidance on these products and does not consider opened-but-unused SUDs to be reused devices that are within the scope of the proposed strategy.

AGENCY INVOLVEMENT IN REUSE

Reports of Patient Injuries

There have been several media reports of catheter tip separations, faulty cataract surgical equipment, and other problems attributed to failure of a reused SUD. A review of Medical Device Reporting (MDR) reports received by CDRH from August 19, 1996 through December 7, 1999, revealed 464 reports (out of approximately 300,000) of adverse events that could possibly be attributed to reuse of a SUD. Of these, 219 involved hemodialyzers; which under certain conditions may be reused in the same patient. The remaining 245 reports spanned approximately 70 different types of products. From these data, we can discern no pattern of failures with reused SUDs that differs from patterns observed with the initial use of SUDs.

MDR reports do not enable accurate assessment of failure rates, whatever the type of device. Detecting SUD problems through the reporting system is even more challenging because the products are often not labeled as SUDs. In addition, device failures may be particularly under-reported (to manufacturers) when the hospital recognizes that the device that failed was a reprocessed SUD. Also, infections that may have resulted from an improperly reprocessed SUD may be hard to trace back to the reused device.

Research Findings

CDRH has implemented a research program to explore safety and effectiveness issues associated with the reprocessing of SUDs. Information on the difficulty of cleaning and disinfecting the devices, the effects of sterilization on materials, the efficacy of resterilization, and alteration in performance criteria have been investigated. CDRH has had the opportunity to examine SUDs after one-time use, compare them to devices that have not been used, and do simulated reuse laboratory studies. Loss of elasticity in inflatable balloons, persistence of blood and biofilms, loss of original lubricants and resultant effect on catheter threading, and crystallization of liquid x-ray contrast material are just some of the factors that we have examined. This research program has expanded our ability to evaluate reports, scientific studies, and comments from the healthcare community.

Hospital infection control programs rarely identify specific incidents of patient infection caused by reuse of SUDs. Our research has shown, however, that the performance of some products is degraded by the effects of biofilms and repeated use. We have presented our laboratory findings at many scientific meetings, as well as through publications in scientific journals. We continue to believe that solid research by industry, academia, and FDA is the best way to understand the issues that need to be addressed and to develop consensus standards for reprocessing practices.

Outreach

The Agency has conducted numerous outreach efforts to further understanding of and participation in this issue. We have convened a public meeting and sponsored videoconferences on our proposed strategy. We have met with individual manufacturers and reprocessors; manufacturers' and reprocessors' trade associations; the American Hospital Association; the Joint Commission of Health Care Organizations (JCAHO); the Health Care Financing Administration (HCFA); and medical professionals and some of their associations on this issue. Two meetings with broad scope that occurred in 1999, were particularly useful in furthering our understanding of this issue.

On May 5-6, 1999, FDA and the Association for the Advancement of Medical Instrumentation co-sponsored a conference on the practice of reprocessing and reusing SUDs. Participants included representatives of health care facilities, firms that reprocess devices, OEMs, national oversight organizations, State governments, academia, medical ethicists, and standards organizations. This provided FDA the opportunity to hear a wide range of views and concerns from individuals and organizations involved in or affected by this practice.

FDA received divergent opinions on how reprocessing and reuse of SUDs should be regulated. Some participants believe that reprocessors should be regulated in the same manner as OEMs and that 510(k) submissions or premarket approval applications (PMAs) demonstrating the safety and effectiveness of the reprocessed device should be required. Others believe that OEMs should be required to provide instructions on how to reprocess their devices unless they can demonstrate that the device cannot be reprocessed. Still others stated that the general controls which the Agency has enforced for third-party reprocessors are sufficient to ensure protection of the public health.

Participants identified the need for additional guidance on reprocessing. Suggestions included: standards to assure that cleaning, disinfection, and sterilization processes are validated and that reprocessing may be performed properly; a determination of what types of devices can and cannot be reprocessed; a classification scheme establishing critical, semi-critical, and non-critical categories for reprocessed devices; and clearer definitions for the terms "reuse," "reprocessing," and "resterilization."

Participants suggested that clinical data and experience on reuse could be obtained through hospitals' existing surveillance activities; long-term clinical studies; the establishment of a clearinghouse for data; National Institutes of Health funds and studies of reprocessing; and research by professional societies with funding provided by OEMs and reprocessors.

FDA held an open meeting, on December 14, 1999, to obtain feedback from stakeholders and interested parties on its proposed strategy on the reuse of SUDs. Twenty-eight public presenters voiced a variety of concerns during the first part of the meeting, and workshops in the afternoon provided attendees with an opportunity to explore particular issues in smaller groups. An Executive Summary, which describes the input we received on many aspects of this complex issue, is available on our website at http//www.fda.gov/cdrh/reuse/1214execsum.pdf.

FDA's CURRENT POLICY

As I noted at the outset, the American public expects, and the Federal Food, Drug, and Cosmetic (FD&C) Act requires, that devices be safe, effective, and manufactured in accordance with GMPs. When a SUD is prepared to be used again by cleaning, repairing, or refurbishing, it is being remanufactured and the FD&C Act provides controls to address these reprocessed devices. However, up until now, FDA has not enforced its regulations in the same manner for OEMs, third-party reprocessors, and hospitals that reprocess devices.

Original Equipment Manufacturers (OEMs)

OEMs are subject to all requirements of the FD&C Act including: registration and listing; premarket notification and approval requirements; submission of adverse event reports under the MDR regulation; manufacturing requirements under the Quality System Regulation; Ubeling requirements; Medical Device Tracking; and Medical Device Corrections and Removals. The Agency has enforced all of these requirements with respect to OEMs.

Third-Party Reprocessors

Third-party reprocessors are subject to the same regulatory requirements as other manufacturers, including premarket requirements. As discussed previously, FDA has required these firms to register and list, has inspected their operations, and issued Warning Letters to third-party reprocessors when we found violations; however, to date, FDA has not actively enforced premarket requirements against third parties. (Note that many devices that are commonly reprocessed are exempt, by regulation, from premarket requirements.)

Hospitals

In November of 1977, FDA issued a guidance informing hospitals that reprocess SUDs that they assume full liability and responsibility for their reprocessing actions and should ensure that the products are adequately cleaned and sterilized, and that device safety, effectiveness, and quality are maintained (Compliance Policy Guide # 300.500). The Agency currently provides no active oversight or routine enforcement for in-hospital reprocessing. If a serious adverse event involving a reprocessed (or any other) device occurred in a hospital, however, FDA can and does investigate and take appropriate action.

FDA's PROPOSED STRATEGY

As I stated earlier, FDA is reevaluating its position on the reuse of SUDs. One of the principal components of FDA's proposed strategy is the establishment of Agency enforcement priorities, concerning regulatory requirements for third-party and hospital reprocessors of SLJDs. FDA proposed to prioritize its enforcement activities based on the degree of risk posed by the reprocessing. To accomplish this process, FDA proposed that it take the following steps:

1. develop a list of commonly-reused SUDs;
2. develop a list of factors to determine the degree of risk associated with reprocessing devices;
3. use that list of factors to divide the list of commonly-reprocessed SUDs into three categories of risk—high, moderate, and low; and
4. develop priorities for enforcement of regulatory requirements for hospitals and third-party reprocessors, based on the category of risk.

Since the announcement of FDA's proposed strategy, FDA has made significant progress. As I mentioned earlier, FDA posted its draft guidances and solicited public comment. The risk categorization scheme was our effort to prioritize the level of risk that could be posed by different reprocessed SUDs in order to reasonably allocate regulatory resources to phase-in equal enforcement of regulatory requirements for all reprocessors. The second draft guidance proposed the timing for enforcement of premarket requirements based on the level of risk assessed under the risk categorization scheme. Specifically, we stated our intention to begin to enforce premarket notification and premarket application requirements within six months of issuance of a final guidance if a reprocessed device was categorized as high risk, within 12 months if the device was categorized as moderate risk, and within 18 months if the device was categorized as low risk.

Many stakeholders who provided input on our draft guidance suggested that we simplify implementation of our policy by aligning our enforcement priorities with the actual device classification. Under that approach, FDA would enforce all premarket requirements first for those reprocessed SUDs that were Class Ed, then phase-in enforcement of premarket requirements for Class Id and Class I reprocessed SUDs. The Agency is evaluating these suggestions and others as we finalize the guidance that will implement our policy.

Although FDA has not previously enforced premarket requirements for third-party reprocessors, FDA currently enforces all other requirements applicable to manufacturers against third-party reprocessors. The issuance of our draft guidance or any final guidance does not and will not change the continuing obligation of third-party reprocessors to comply with those provisions of the FD&C Act. Under its draft plan, however, FDA would not immediately enforce those requirements for hospitals, in order to give them an opportunity to become familiar with the applicable regulations and procedures.

I would like to give a couple of examples of how our increased oversight would affect reprocessors of devices of disparate complexity and risk. Oral and nasal catheters, fairly simple devices, are currently Class I and exempt from premarket notification. They would be considered "low risk" under the risk categorization scheme I just described. Within a certain period of time after the guidance becomes final, FDA will actively enforce all non-premarket requirements for hospitals that reprocess oral and nasal catheters, just as we currently do for OEMs and third-party reprocessors, including registration, listing, manufacturer adverse event reports, labeling, corrections and removals, tracking, and quality system manufacturing requirements. Percutaneous transluminal angioplasty (PTAQ catheters are Class HI devices that we consider "high risk" under the scheme. Based on our own studies, we have determined that cleaning and sterilizing these devices are very difficult. After the final guidance is issued, FDA will actively enforce premarket requirements for hospitals and third parties that reprocess PTACs. Within a relatively short time period, FDA will enforce requirements for those hospitals and third parties to submit PMAs demonstrating that their reprocessing of PTACs is safe and effective, in addition to conforming to the general controls of the FD&C Act.

At this time, the Agency is limiting its focus to SUD reprocessing by third parties and hospitals. The draft SUD enforcement guidance does not apply to permanently

implantable pacemakers (reuse of those devices is already addressed in a Compliance Policy Guide), "opened-but-unused" SUDs, hemodialyzers, and healthcare facilities that are not hospitals.

NEXT STEPS

Issuance of Final Guidance Documents

The guidance documents I mentioned are not final, nor are they in effect at this time. The drafts, which relied on input from earlier public meetings, have been out for comment since February 2000 and the comment period ended on April 11, 2000. We are now completing review of the comments we received on these draft documents, and will be issuing final guidance documents in the very near future. As I noted at the outset, the Agency received strong support for its proposed regulatory strategy for third parties and hospitals that engage in the reprocessing and reuse of devices labeled for single use in the United States.

Phased-In Enforcement

In general, our stakeholders and interested parties endorsed phased-in enforcement of our strategy for applying our regulations for OEMs, third-party, and hospital reprocessors in the same manner. As soon as our final guidance issues, FDA is planning to phase-in the enforcement of regulatory requirements for third parties and hospitals that reprocess SUDs.

Collaboration with Other Parties

The direction in which we are headed could impact significantly on the Agency's resources, particularly for conducting inspections of hospitals that reprocess SUDs. We will be collaborating with third parties, such as JCAHO, HCFA, and other regulatory bodies that currently perform oversight of the health care sector, to assist us in implementing our policy.

Outreach

We will be continuing our outreach efforts to ensure that the health care community, manufacturers, reprocessors, patients, and the public are fully aware of the issues involving the reprocessing and reuse of SUDs. Our efforts will include talk papers, public health notifications, and lay articles on an FDA web page. We plan special efforts to communicate and work with the hospital community affected by FDA's requirements for reprocessors.

SUD Labeling

We also will continue to consider changes to the labeling of SUDs by OEMs. One option the Agency is considering is requesting OEMs who label their devices "single-use" to provide, as part of the device's labeling, any information of which they are aware regarding the potential risks associated with reusing their SUDs. This information would serve as a caution to users and reprocessors who might attempt to reprocess these SUDs.

Institute an Expanded Research Program for Reuse

The Agency has conducted several in vitro studies on reused SUDs and is considering additional studies on the effects of reprocessing. Expansion of our research efforts may facilitate collaboration with stakeholders and interested parties to conduct more in vivo and in vitro studies.

General Accounting Office (GAO) Report

The Agency is pleased that Congress asked GAO to look into the practice of SUD reprocessing in the United States. We recently provided comments to GAO on the draft report. Overall, we believe the report provided a balanced analysis of a difficult issue. The draft report noted that FDA's strategy represented a reasonable approach given Agency resources. The report also stressed the need for FDA to educate hospitals about reprocessing requirements and the Agency agrees that this type of outreach effort will be essential to successful implementation. The report also highlights the need for other Federal agencies to help implement the strategy. The Agency is currently working with JCAHO to employ their expertise and resources in this area.

CONCLUSION

Mr. Chairman, although we have no data to indicate that people are being injured or put at increased risk by the reuse of SUDs, the results of our own research and the information provided by various stakeholders have convinced us that this growing practice needs closer scrutiny and oversight. We are committed to addressing reuse in an open and cooperative fashion with the industries involved, the health care community, the public, and, of course, the Congress to craft a policy that is reasonable yet effective in minimizing the risks associated with this practice. We believe we are on schedule to implement a reasonable strategy that will treat all reprocessors of SUDs in the same manner. Thank you for the opportunity to be here today. I am happy to answer any questions you may have.

The CHAIRMAN. I do not know what that was.

Ms. HEINRICH. It is a fly. [Laughter.]

Senator DODD. Did you get it?

The CHAIRMAN. Overly friendly. [Laughter.]

Senator DODD. You should hear the Defense Department.[Laughter.]

The CHAIRMAN. Our next witness is Dr. Janet Heinrich of the General Accounting Office, GAO. Dr. Heinrich is a graduate of the University of Michigan School of Nursing. She received a master's of public health and a doctorate of public health from Yale University, Department of Epidemiology and Public Health in the School of Medicine.

Dr. Heinrich is Associate Director, Health Financing and Public Health Issues, with the U.S. General Accounting Office. She was Director of the American Academy of Nursing for 7 years, and before that, served as the Director of Extramural Programs, National Institute of Nursing Research at NIH. Welcome, and please proceed.

Ms. HEINRICH. Thank you. I am pleased to have the opportunity to testify as the committee considers issues relating to the reprocessing and reuse of medical devices marketed for single use. Reprocessing involves cleaning, sterilizing a device and verifying that it functions properly. This practice, especially with devices labeled for single use and used on another patient, raises possible health concerns regarding the potential risk of infection and device malfunction.

I will summarize the key findings of our recent report prepared for you, this committee, and Senator Durbin, which focuses on the extent of single-use device reprocessing, the health risks associated with this practice, the cost savings experienced by hospitals, and FDA's oversight. We looked only at the practice of reprocessing single-use devices for use on another patient. In other words, we did not examine devices that were opened but not used.

FDA regulates the safety and effectiveness of medical devices. Their requirements for approving devices depend on the potential for harming patients with greater scientific data required for higher risk devices. The single-use devices are those for which manufacturers have not submitted evidence to FDA that they can be used multiple times. FDA's approval of a single-use device means that it can be used safely and reliably once but not necessarily that it cannot be used more than once if it is appropriately processed.

While the exact size of the reprocessing industry is unknown, it clearly is a small part of the overall medical device market. FDA has identified 13 third-party reprocessing companies although there are likely more in operation. Also, some small fraction of the approximately 6,000 hospitals and 2,700 ambulatory surgery centers in the U.S. reprocess in-house. Surveys indicate that approximately 20 to 30 percent of U.S. hospitals reused at least one type of device and that of those another third of those contracted with third-party companies.

The frequency of reprocessing varies widely among different devices and most hospitals reprocess only a few types. The safety of reprocessing some types of devices has been established by clinical studies to be relatively safe and has shown both that the reprocess-

ing procedures can be accomplished and that patient outcomes are not adversely affected.

The hospital infection control practitioners, risk management executives, patient safety experts we interviewed told us that careful reprocessing of the types of devices that can be properly cleaned and sterilized does not pose an additional risk to patient health.

Hospital infection experts at the CDC told us that the evidence showed that such reprocessing poses minimal health risk. We found little indication in reports of adverse events related to medical devices that single-use device reprocessing is unsafe. However, it is also clear that some devices cannot be safely reprocessed, that procedures for safe reprocessing are not always followed, and that the limitations of the information available argue for better monitoring.

Current surveillance systems for adverse events do not detect all infections and injuries from the use of medical devices in general. It is also well known that surveillance systems based on spontaneous reports by health care providers and manufacturers are plagued by underreporting and incomplete records.

Although there is some debate about how to calculate the true cost of reprocessing, hospitals that use reprocessing told us that they save money by doing so. Third-party firms charge hospitals and ambulatory surgery centers approximately one-half of the price of a new device. In-hospital reprocessing can cost less than ten percent of the price of a new device.

With the new FDA framework, hospitals will be expected to satisfy all the requirements now faced by third-party firms and manufacturers, such as registering with FDA, telling FDA which devices they reprocess, fulfilling additional medical device reporting requirements, using reprocessing procedures that meet the standards for good manufacturing practices, and facing inspection by FDA. Also, hospitals and third-party reprocessing firms will be required to meet all applicable premarket requirements as if they were seeking to market a new device including clinical trials, labeling requirements, and instructions for use will need to be followed as well.

The new framework excludes nonhospital health care facilities that reprocess and will thus maintain the inconsistency of the current policy by exempting some from FDA oversight. Implementation of this new framework will face a number of barriers. These include hospital and third-party firms' inexperience with FDA's regulations, FDA's ability to identify all of the reprocessors, and their ability to review and inspect these facilities.

In conclusion, the evidence that is available suggests that some single-use devices can be safely reprocessed if appropriate cleaning, testing, sterilization procedures are carefully followed. However, reprocessing is not invariably safe and for this reason greater FDA oversight of the single-use device reprocessing is warranted. Mr. Chairman, this concludes my remarks and I will be happy to answer any questions that you and the committee would have.

The CHAIRMAN. Thank you very much. That was a very helpful statement.

[The prepared statement of Ms. Heinrich follows:]

PREPARED STATEMENT OF JANET HEINRICH

Mr. Chairman and Members of the Committee: I am pleased to have the opportunity to testify as the committee considers issues relating to the reprocessing and reuse of medical devices marketed for single use. As you know, medical devices approved for sale in the United States as single-use devices (SUD) sometimes are reprocessed and used again on other patients.[1] Reprocessing involves cleaning and sterilizing a device and verifying that it functions properly. The practice of SUD reprocessing reduces the costs of medical devices for hospitals and other health care facilities, but it also raises public health concerns, primarily regarding the potential risks of infection and device malfunction, and has led to complaints that the Food and Drug Administration (FDA) has failed to provide consistent oversight. You asked us to discuss the results of our recent report on this issue.[2]

I will summarize the key findings of our report, which focuses on (1) the extent of SUD reprocessing, (2) the health risks associated with SUD reprocessing, (3) the cost savings from SUD reprocessing, and (4) FDA's oversight of SUD reprocessing. We looked only at the practice of reprocessing SUDs for use on another patient; we did not examine devices approved for marketing as reusable, the resterilization of opened but unused devices, or devices reprocessed for additional use on the same patient. SUDs are those devices for which manufacturers have not submitted evidence to FDA that they can be used multiple times; this does not necessarily mean that they cannot be used more than once if appropriately reprocessed.

It is clear that some health care facilities have chosen to reprocess and reuse some kinds of SUDs, but accurate and comprehensive information about the number of facilities that use reprocessed SUDs and the types of SUDs that are reprocessed is not available. According to various surveys, approximately 20 to 30 percent of American hospitals reported that they reuse at least one type of SUD and at least one-third of the hospitals that do so contract with third-party reprocessing companies. The results of clinical studies show that selected devices can be reprocessed safely if appropriate procedures are followed and closely monitored, a view shared by many professional organizations and infection control experts. However, this does not mean that SUD reprocessing is always safe. Current medical device surveillance systems almost certainly do not detect all infections and injuries resulting from the use of reprocessed SUDs, or from the use of medical devices in general, and there is general agreement that many types of SUDs cannot be effectively cleaned and sterilized. Reprocessing SUDs can produce substantial cost savings, with independent reprocessing firms charging hospitals approximately one half the price of a new device for a reprocessed device, while the in-house cost of reprocessing some devices can be less than 10 percent of the price of a new device. FDA is about to institute a new regulatory framework for SUD reprocessing that will require independent reprocessing firms and hospitals to obtain FDA's approval before they can reprocess many devices labeled for single use. The framework will provide FDA with more information and strengthen its oversight of reprocessing. However, there are significant barriers to the framework's successful implementation.

BACKGROUND

FDA is responsible for ensuring the safety and effectiveness of medical devices sold in the United States, ranging from bandages and thermometers to cardiac catheters and artificial hearts. Approximately 80,000 to 100,000 models of medical devices are currently in use in the United States, and the domestic market for medical devices totaled roughly $56 billion in 1999. FDA regulates the safety and effectiveness of medical devices, the packaging and labeling that describe how they should be used, and the facilities that manufacture them. FDA's requirements for approving devices for marketing depend on the devices' potential for harming patients, with greater data and documentation required for higher-risk devices.

Generally, FDA can evaluate applications to market new devices only in terms of a device's intended use as described on its label.[3] Manufacturers that wish to market a device for single use need to convince FDA only that it can be used safely and effectively once-they do not need to demonstrate that the device cannot be used more than once. Thus, FDA's approval of a device for single use means that a device can be used safely and reliably once, not necessarily that it cannot be used safely and reliably more than once if it is appropriately reprocessed. Conversely, manufacturers that wish to market a device as reusable must either provide data dem-

[1] SUDs are also referred to as disposable devices because they are intended to be discarded after one use.

[2] Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted (GAO/HEHS-00-123, June 20, 2000).

[3] Food and Drug Administration Modernization Act of 1997 (P.L. 105-115), Sec. 205(b), adding Sec. 513(i)(1)(E)(i) to the Federal Food, Drug, and Cosmetic Act.

onstrating that the device will be safe and effective for a specified number of uses, or provide a measure to determine whether it will still meet performance specifications after reprocessing. Manufacturers must show that the device can be cleaned and sterilized and that its function will not degrade with repeated uses. Devices that are not marketed as reusable are sold for single use.[4]

THE EXTENT OF REPROCESSING

Third-party reprocessing firms and some hospitals and other health care facilities reprocess SUDs. While the exact size of the reprocessing industry is unknown, it is clearly only a small part of the medical device industry. For example, FDA has identified only 13 third-party reprocessing companies, although it suspects that more are in operation. Last year, a trade association representing major third-party reprocessing firms said that its members collectively received about $20 million annually for their services. Evidence indicates that only a minority of the approximately 6,000 hospitals and 2,700 ambulatory surgery centers in the United States reprocess SUDs in-house.

While it is clear that some health care facilities have chosen to reprocess and reuse some kinds of SUDs, neither FDA nor any other organization has accurate and comprehensive information about the number of facilities that use reprocessed SUDs or the types of SUDs that are reprocessed. We found six surveys about SUD reprocessing conducted by professional associations and other groups. The surveys typically asked members of selected professional groups to describe the SUD reprocessing practices at the institution with which they are affiliated. Most surveys found that approximately 20 to 30 percent of American hospitals reused at least one type of SUD and that at least one-third of the surveyed hospitals that reused SUDs contracted with independent reprocessing companies. While the results of the various surveys are fairly consistent, it is difficult to assess the validity of the findings because the response rates for the surveys are low, with only one survey having a response rate greater than 50 percent, and health care facilities that use reprocessed SUDs may have disproportionately declined to respond to the surveys. The surveys also may not completely capture the use of reprocessed SUDs in ambulatory surgery centers, physicians' practices, or other nonhospital facilities.[5]

The frequency of reprocessing varies widely among different devices, and most hospitals that reuse SUDs reuse only a few types of devices. For example, electrophysiology (EP) catheters, devices inserted into the heart to measure and coffect cardiac rhythm disorders, have been reprocessed for 20 years, even though all models of them were approved for single use only. Some types of EP catheters are relatively easy to clean, sterilize, and test. They also are expensive enough for hospitals to consider the cost savings from reprocessing sufficient to warrant considering reuse. Several hospitals told us that EP catheters were among the very few SUDs they reused. Conversely, gastrointestinal (GI) biopsy forceps are more difficult to reprocess. The forceps are long and have hollow tubes and delicate mechanisms that make them harder to clean and sterilize, and none of the gastroenterology centers we contacted said that they reused these devices.

AVAILABLE EVIDENCE SUGGESTS THAT SOME TYPES OF SUDS CAN BE SAFELY REPROCESSED

The safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of reprocessed SUDs. For example, several studies have documented the safe reprocessing and reuse of EP catheters. One study of more than 14,000 EP procedures found that the overall rate of patient infections was very low and did not differ between clinical centers that reused EP catheters and centers that used each catheter only once.[6]

The hospital infection control practitioners, risk management executives, and patient safety experts we interviewed told us that careful reprocessing of the types of SUDs that can be properly cleaned and sterilized does not pose an additional risk to patient health. Hospital infection experts at the Centers for Disease Control and Prevention told us that the evidence showed that SUD reprocessing poses minimal public health risk. Risk management professionals told us that the hospitals they worked with had not received any claims of patient injury caused by the use of reprocessed SUDs. With the exception of groups representing device manufacturers, all of the professional organizations with positions on SUD reuse that we contacted

[4] FDA also has the authority to require a manufacturer to change the label of a device that it markets for an intended use other than that on the label and that poses a health risk.

[5] This is because some of the surveys did not include nonhospital facilities.

[6] S. O'Donoghue and E.V. Plata, "Reuse of Pacing Catheters: A Survey of Safety and Efficacy," Pacing and Clinical Electrophysiology, Vol. 11, No. 9 (1988), pp. 1279-80.

or that submitted comments to FDA on the agency's regulatory proposal expressed at least qualified support for SUD reprocessing and reuse. None sought to ban SUD reprocessing, although some supported FDA's plan to more closely regulate SUD reprocessing. These organizations included groups representing physicians, nurses, in-hospital sterilization professionals, infection control practitioners, and health care facilities.

We found little indication in reports of adverse events related to medical devices that SUD reprocessing is unsafe. Only a very small percentage of the reports FDA has received through its Medical Device Reporting (MDR) program concerned patient adverse outcomes associated with reused SUDs, although this program probably underestimates the number of injuries from reprocessed SUDs.[7] For a roughly 3-year period ending in December 1999, FDA's Manufacturer and User Facility Device Experience database received nearly 125,000 reports of patient injuries, device malfunctions, or other potential problems associated with SUDs. FDA told us that 1,131 (less than 1 percent) of those reports involved SUDs that had been reprocessed but that nearly 700 of the reports concerned dialysis equipment that was reprocessed for use on the same patient. Only 49 of the reports were for SUDs included on FDA's list of frequently reprocessed SUDs, and it is not known whether those injuries and malfunctions were caused by reprocessing, by device failure unrelated to reprocessing, or by some other aspect of the medical procedure.[8]

Several of the public reports we identified of patient adverse events allegedly related to SUD reprocessing were inaccurate, did not involve the type of reprocessing discussed here, or were difficult to interpret. For example, it was alleged that SUD reuse caused increased rates of pneumonia in one group of children.[9] This was supported by a study of home use of tracheostomy tubes in children with breathing difficulties.[10] This is not relevant to the current discussion because the reused tubes were cleaned at home with hydrogen peroxide, vinegar, or soap and water for use on the same child, not reprocessed by hospitals or third-party companies for use on other patients. Likewise, FDA received a report that the tip of a reused EP catheter broke off and lodged in a patient's heart. However, FDA also received two reports of similar injuries resulting from procedures with new EP catheters.

SUD Reprocessing Not Always Safe

It is also clear that some SUDs cannot be safely reprocessed, procedures for safe reprocessing are not always followed, and the limitations of the information available about SUD reprocessing argue for monitoring the practice. FDA researchers, original device manufacturers, and third-party reprocessors all agree that many types of SUDs cannot be reprocessed safely. There is also agreement that, even for some categories of SUDs that can be reprocessed, some models can be thoroughly cleaned and sterilized while others cannot. For instance, two third-party reprocessing firms told us that they distinguish for clients particular device models that can, or cannot, be successfully reprocessed.

For devices that can be reprocessed safely, cleaning and sterilization procedures are not always followed correctly. For example, a 1997 survey of gastrointestinal endoscopy physicians found that about one-quarter of endoscopic facilities failed to follow all of a professional association's guidelines for cleaning and sterilizing endoscopic instruments.[11] Also underscoring the potential risks of SUD reprocessing, infection outbreaks occur occasionally that are due to sterilization failures for devices approved for marketing as reusable.[12]

Device manufacturers have forwarded to FDA reports of allegedly damaged, unclean, or nonsterile reprocessed SUDs taken from hospital stocks that had been reprocessed by third-party reprocessing firms. FDA found that at least one of these claims had merit. In March 1999, a manufacturer told FDA that six reprocessed GI biopsy forceps it retrieved from a Florida hospital were not sterile. The devices were

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[7] This is because the information on MDR reports that identifies SLTDs as reused is inconsistent and probably incomplete. For example, an FDA official told us that FDA had received only six MDR reports that mentioned a third-party reprocessing firm by name and that three of them were for the same incident.

[8] The remaining reports were for devices other than those on FDA's list of frequently reprocessed devices or for devices that were reused on the same patient.

[9] Statement of Robert H. O'Holla, before the Oversight and Investigations Subcommittee, House Commerce Committee (Feb. 10, 2000).

[10] "S.C. Baling and others, "Parental Report of Pediatric Tracheostomy Care," Archives of Physical Medicine and Rehabilitation, Vol. 79, No. 11 (1998), pp. 1367-69.

[11] "R.J. Cheung and others, "GI Endoscopic Reprocessing Practices in the United States."

[12] "CDC, "Nosocomial Infection and Pseudoinfection from Contaminated Endoscopes and Bronchoscopes-Wisconsin and Missouri," Morbidity and Mortality Weekly Report, Vol. 40, No. 39 (1991), pp. 675-78; and CDC, "Bronchoscopy-Related Infections and Pseudoinfections-New York, 1996 and 1998," Morbidity and Mortality Weekly Repo , Vol. 48, No. 26 (1999), pp. 557-60.

labeled for single use only and had been reprocessed by a third-party reprocessing company. These biopsy forceps are nearly 8 feet long, and the sterility testing procedure used by the manufacturer involved cutting the devices into segments to allow better access to the center portions of the hollow tubing. Using established test procedures that did not segment the biopsy forceps, both FDA and the reprocessing firm subsequently tested devices from the same lot and found them to be sterile. FDA now believes that the sterility test protocol it used was not the best one for these devices, and it is preparing a new protocol. Although there is no evidence that these reprocessed devices have harmed patients, this case demonstrates the possibility that some reprocessed SUDs sterilized according to current protocols might not be free of bacterial contamination.

Current surveillance systems for medical errors and adverse events almost certainly do not detect all infections and injuries resulting from the use of reprocessed SUDs, or from the use of medical devices in general. It is well known that surveillance systems based on spontaneous reports by health care providers and manufacturers are plagued by underreporting, incomplete reports, and other problems.[13] In addition, FDA officials and infection control experts told us that it is often difficult to identify the source of infections in individual patients, and it can be particularly difficult to trace infections back to the use of specific medical devices.

SUD REPROCESSING REDUCES HOSPITAL COSTS FOR MEDICAL DEVICES

Reprocessed SUDs cost less than new devices. Independent reprocessing firms charge hospitals and ambulatory surgery centers approximately one-half of the price of a new device for each reprocessed SUD, while three hospitals that reprocess EP catheters inhouse told us that their reprocessing costs were less than 10 percent of the price of a new device. Although there is some debate about how to calculate the true costs of reprocessing, hospitals that use reprocessed SUDs told us that they save money by doing so. For example, hospitals gave us estimates for their savings from reusing EP catheters ranging from $115,000 to $1 million annually.

The exact prices paid for new SUDs are arrived at during negotiations between individual manufacturers and individual purchasers. The competitive alternative offered by SUD reprocessing appears to have affected negotiations between manufacturers and purchasers and may have caused some manufacturers to lower their prices to some purchasers. For example, we obtained copies of marketing materials from a manufacturer of single-use sequential compression devices offering to reduce prices if the purchasing hospital signed a contract stipulating that it would not reprocess the devices. For two hospitals we contacted, manufacturers offered to reduce the price of new EP catheters by as much as one-half, matching the price of third-party reprocessing, if the facilities would agree to not reprocess the devices. A major third-party reprocessing firm told us that some hospitals stopped using its services when offered this arrangement by manufacturers. We were not able to determine how often manufacturers offer these price breaks.

FDA'S PROPOSED REGULATORY FRAMEWORK WELL EXTEND REQUIREMENTS FACED BY MANUFACTURERS TO MOST SUD REPROCESSORS

FDA categorizes all entities that reprocess SUDs-including third-party reprocessing firms, hospitals, and ambulatory surgery centers-as device manufacturers, and therefore they are technically required to comply with good manufacturing practices, FDA inspection, and manufacturers' adverse events reporting regulations. FDA has enforced these provisions for third-party reprocessing firms but not for hospitals and other health care facilities that reprocess SUDs. Currently, manufacturers that want to market a reusable device must submit data to FDA that convinces the agency that a device can be safely reprocessed for a set number of times without compromising its function. While third-party firms must register with FDA and meet FDA's standards for good manufacturing practices, they can reprocess SUDs without seeking premarket approval from FDA.

A difficulty with the current policy has been FDA's inability to inspect all third-party reprocessors because it has been unable to identify them. This month, FDA officials told us that FDA had identified 14 reprocessing facilities operated by 13 different reprocessing firms and that the agency had inspected all but two of those facilities. FDA suspects that there are more third-party reprocessors that have not registered with the agency.

FDA has proposed a new regulatory framework that will make major changes to the oversight of SUD reprocessing. The framework will extend enforcement of all of FDA's requirements for device manufacturers to hospitals that reprocess SUDs

[13] See Adverse Events: Surveillance Systems for Adverse Events and Medical Errors (GAO/T-HEHS-00-61, Feb. 9, 2000).

and third-party reprocessing firms.[14] There will be three major changes. First, hospitals will be expected to satisfy all the requirements now faced by third-party reprocessing firms, such as registering with FDA, telling FDA which devices they reprocess, fulfilling the MDR reporting requirements for manufacturers, using reprocessing procedures that meet the standards for good manufacturing practices, and facing inspection by FDA. Second, hospitals that reprocess SUDs and third-party reprocessing firms will be required to meet all applicable premarket requirements. That is, they will have to submit relevant documentation to FDA as if they were seeking to market a new device. Finally, all reprocessors will be required to follow general requirements for labeling SUDs, including providing adequate instructions for use.[15] FDA plans to issue a final guidance document in July 2000, with the new requirements taking effect over an 18-month period starting then.

FDA's proposed regulatory framework specifically exempts opened but unused SUDs. The proposed framework also does not apply to health care facilities other than hospitals that reprocess SUDs in-house. By at least temporarily excluding ambulatory surgery centers and other nonhospital health care facilities from regulation, the proposal maintains the inconsistency of the current policy by exempting some reprocessors from FDA oversight.

SUD Reprocessors and FDA May Have Difficully Implementing the New Framework

FDA's proposed regulatory framework imposes a structure designed to oversee the manufacture of new medical devices onto the different enterprise of SUD reprocessing. Implementation of this new framework will face a number of barriers, including SUD reprocessors' inexperience with FDA's regulations for medical device manufacturers. Hospitals that reprocess SUDs have no experience with FDA's regulation of medical devices and device manufacturers, even though FDA technically considers them to be device manufacturers now. And, while third-party reprocessing firms already collect some of the data FDA will require for premarket approval of reprocessed SUDs, their ability to adjust to the new requirements is not assured.

FDA will probably not be able to identify all of the reprocessors that will be subject to the new regulatory framework, at least in the short term. In addition, although it is engaged in an outreach effort to educate hospitals that reprocess SUDs in-house about the new requirements, we believe that FDA will find it difficult to identify reprocessing hospitals unless they voluntarily register with the agency.

The potentially large number of additional premarket applications and manufacturing facilities to inspect could overburden FDA's already stretched resources. The number and complexity of marketing applications that will be submitted for reprocessing is unknown, as is the number of hospitals that will register with the agency. But FDA could receive many premarket applications because applications are required from each entity for each device that it wishes to reprocess. A large number of applications may impede FDA's ability to oversee reprocessing and may compromise its work in other areas. Premarket submissions for reprocessing will be placed in the same queue as marketing applications for new medical devices and an FDA official told us that this additional work may decrease the percentage of marketing applications for new devices that are reviewed in a timely manner.

FDA's New Framework May Decrease SUD Reprocessing in Hospitals

FDA's proposed framework imposes significant new requirements on institutions that reprocess SUDs. FDA officials, hospital administrators, physicians, and device manufacturers all told us that hospitals will be much less likely to maintain in-house SUD reprocessing operations under the new framework. Some hospitals that currently reprocess in-house are likely to contract with third-party reprocessing firms for that work. At least some third-party firms anticipate an increase in business.

CONCLUSIONS

The evidence suggests that some SUDs can be safely reprocessed if appropriate cleaning, testing, and sterilization procedures are carefully followed. However, SUD reprocessing is not invariably safe, and relatively little is known about the practice of SUD reprocessing in health care facilities. For this reason, FDA has taken steps to increase its oversight of SUD reprocessing. Nonetheless, the new framework is cumbersome and will be difficult to implement.

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[14] FDA, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (Rockville, Md.: FDA, Feb. 2000).

[15] Neither the hospitals nor the third-party reprocessors we contacted now include instructions for use on their labels because reprocessed devices ordinarily are returned to facilities that already have instructions from the manufacturers original labeling of the device. To the extent that these required instructions infringe on the copyrighted instructions of the original manufacturers, it may be difficult for reprocessors to meet this requirement.

This concludes my prepared statement, Mr. Chairman. I will be happy to respond to any questions that you or Members of the Committee may have.

CONTACTS AND ACKNOWLEDGEMENTS

For future contacts regarding this testimony, please call Janet Heinrich at (202) 5127119. Key contributors include Lisanne Bradley, Marcia Crosse, Martin T. Gahart, Janina R. Johnson, and Stefanie Weldon.

The CHAIRMAN. I will now turn to Senator Kennedy.

OPENING STATEMENT OF SENATOR KENNEDY

Senator KENNEDY. Thank you very much, Mr. Chairman. I appreciate your holding this very important hearing. It is good to see our friend and colleague from Illinois, Senator Durbin, who has been very interested in this issue and has been a real leader, and to welcome him to the discussions we are having today.

I commend the GAO for its study on the reprocessing of single-use medical devices. As the GAO reported, only limited data exists on which single-use devices can and cannot be safely reprocessed and which reprocessing methods are effective. The dangers posed by inadequate reprocessing are real and they do require solutions.

In their effort to reduce costs, more than a third of all hospitals across the country now reuse medical devices that are labeled by the original manufacturer as disposable or for single-use only and more than a million devices a year are reprocessed and then used on patients without their knowledge and without a determination by the FDA that the devices are still safe and effective.

Inadequate cleaning and sterilization can lead to serious infections in patients and hospital staff if the devices are used again. The cleaning and sterilization process itself can impair the operation of a single-use device. physical, mechanical and electrical properties can be altered when the device is subjected to harsh chemicals, high temperatures, pressures, gases or the removal of debris. Even the proper use of the device in the first patient can alter the device.

The Medical Device Amendments of 1976 gave the FDA the authority to exercise premarket control over medical devices to protect patients. The FDA requires that before a device manufacturer begins selling a single-use device as reusable in other patients, the manufacturer must file appropriate data demonstrating the safety and efficacy of the reprocessed device, the same premarket requirement that must be met for selling the original device.

We should expect the same requirement to apply when a reprocessor claims the device can be reused. But this requirement has only been applied to the manufacturer and not to hospitals, other providers or firms that do the reprocessing. When hospitals or reprocessors prepare a single-use only device for use again in another patient, they do not supply the FDA with any information on the safety and efficacy of the device.

And the decision on which devices can be reprocessed and what reprocessing methods can be used should be based on sound science; yet, that is not the case today and patients are at risk. The GAO report highlights the lack of data available to regulators and the public. Information is needed on who is reprocessing, which single-use devices can be safely reprocessed, what methods should be used to reprocess, and how should reprocessed devices be tested before they are reused in patients.

Patients expect that a reused device will be as safe and effective as when first used. It is time for the FDA to strengthen its regulation of reprocessing. I commend the FDA for recognizing the potential public health risk and for taking appropriate steps to ensure the safety and effectiveness of reprocessed devices. Only by basing these decisions on sound science can we give patients the assurance of safety they expect from our health care system.—[The prepared statement of Senator Kennedy follows:]

PREPARED STATEMENT OF SENATOR KENNEDY

I commend the Chairman for holding today's hearing on this important public health issue. I also commend the GAO for its study on reprocessing single-use medical devices. As the GAO reported, only limited data exists on which single-use devices can and can't be safely reprocessed and which reprocessing methods are effective. The dangers posed by inadequate reprocessing are real, and they require solutions.

In their effort to reduce costs, more than a third of all hospitals across the country now reuse medical devices that are labeled by the original manufacturer as "disposable" or "for single-use only." More than a million devices a year are reprocessed—and then used on patients without their knowledge and without a determination by the FDA that the devices are still safe and effective.

Many single-use devices are made from heat-sensitive plastics. Others have intricate or inaccessible parts which can be difficult, if not impossible, to clean. Still others have long narrow tubing, crevices, coils, joints, and porous surfaces where dangerous contaminants can collect. Some hospitals and third-party firms reprocess highly invasive devices contaminated with blood and tissue during use, such as balloon angioplasty catheters for opening clogged arteries to the heart.

Inadequate cleaning and sterilization of these devices can lead to serious infections in patients and hospital staff if the devices are used again.

The cleaning and sterilization process itself can impair the operation of a single-use device. Physical, mechanical and electrical properties can be altered when the device is subjected to harsh chemicals, high temperatures, pressure, gases, or the removal of debris. Even the proper use of the device in the first patient can alter the device.

When the FDA conducted studies on cleaned and resterilized balloon angioplasty catheters, it found that many of the narrow spaces in these catheters remained contaminated with blood, and that the balloons no longer inflated properly.

Other independent studies on biopsy forceps, which are used to collect tissue samples from the colon, showed that over 60 percent remained contaminated with blood, tissue, or fecal matter. The devices in this study were taken from hospital shelves, where they were waiting for reuse on future patients.

The Medical Device Amendments of 1976 gave the FDA the authority to exercise premarket control over medical devices. To protect patients, the FDA requires that before a device manufacturer begins selling a single-use device as reusable in other patients, the manufacturer must file appropriate data demonstrating the safety

and efficacy of the reprocessed device—the same premarket requirement that must be met before selling the original device. We should expect the same requirement to apply when a reprocessor claims that a device can be reused.

But this requirement has only been applied to the manufacturer, and not to hospitals, other providers, or firms that do the reprocessing. When hospitals or reprocessors prepare a single-use only" device for use again in another patient, they do not supply the FDA with any information on the safety and efficacy of the device. The decision on which devices can be reprocessed and what reprocessing methods can be used should be based on sound science. Yet that is not the case today, and patients are at risk.

Some hospitals claim that reprocessing is safe, because they've been engaged in this practice for years without a problem. However, many hospitals do not adequately track adverse events that might result from a reprocessed device. Even the doctors and nurses who use the devices don't always know they have been reprocessed.

The GAO report highlights the lack of data available to regulators and the public. Information is needed on who is reprocessing, which single-use devices can be safely reprocessed, what methods should be used to reprocess, and how reprocessed devices should be tested before they are reused in patients.

Patients expect that a reused device will be as safe and effective as when first used. It is time for the FDA to strengthen its regulation of reprocessing. I commend the FDA for recognizing the potential public health risks, and for taking appropriate steps to ensure the safety and effectiveness of reprocessed devices. Only by basing decisions on sound science can we give patients the assurance of safety they expect from our health care system. I look forward to hearing from today's witnesses.

Senator KENNEDY. You will ask questions, Mr. Chairman, and then I will follow with any other questions.

The CHAIRMAN. That is right. I also want to welcome Senator Durbin, who has been very active in this area. And in our questioning period, I will turn to you also and let you proceed as a member, not now.

Senator DODD. You got to wait awhile.

The CHAIRMAN. You got to wait awhile. [Laughter.]

Senator KENNEDY. She can go ahead of you, too.

Senator DODD. We are all going to go ahead of you. Now do you feel welcome?

Senator Durbin. I will come back after lunch. [Laughter.]

Senator COLLINS. I am used to the chairman ignoring me. I have gotten used to it. [Laughter.]

The CHAIRMAN. Come sit up here. [Laughter.] Dr. Feigal, GAO reports that they have found third-party reprocessors that FDA had not previously identified. Exactly how many reprocessors has FDA identified and how will FDA regulate the practice of unknown reprocessors?

Dr. FEIGAL. Well, just as there are people that the IRS does not know about, there are device manufacturers that do not report to us until we find them, and in this case, as you might expect, part

of this industry may not have recognized until recently that we regulated them.

So we have been finding them over the past year as they have been submitting comments to our practices, and I think in the GAO report, they cited that they found one additional which they notified us about. I think as we begin the process of working with the hospitals, we will find that the third parties, there are currently less than three dozen reprocessors, commercial reprocessors, that we know about. We have been actively inspecting those as our first priority since they serve multiple institutions.

The CHAIRMAN. With respect to that, of course, this is an unusual situation, with the original manufacturer desiring to keep selling more and more, the manufacturer has a real desire that you shut all the reprocessors down. On the other hand, for the purposes of efficiency and cost savings, where do you draw the line, and who is responsible if something goes wrong?

Dr. FEIGAL. Well, the easiest way to conceptualize the approach, and I think it addresses some of the concerns Senator Kennedy raised, is that the difference between the original manufacturer and the reprocessor is that the reprocessor's starting material is the used device and then the question becomes how suitable is that as a starting material for a product that needs to be able to perform in a safe and effective way?

The original manufacturer is beginning with raw materials or some other types of components that have not been used before. And so we look at the reprocessor as another manufacturer who has to meet all of the usual manufacturing requirements to show us that they have high quality starting materials, that they process them properly, and that they will perform appropriately when they are put into place. And I think it is actually a relatively simple concept.

The CHAIRMAN. Before last year's IOM report on medical errors, it would have been hard to imagine that there were up to 98,000 fatalities last year with respect to medical errors. You report that there is little evidence of a public health threat from reprocessing. Does this mean that a threat does not exist?

Dr. FEIGAL. I think that the types of problems that are happening with reused devices only in unusual circumstances lead to patient injuries. We recognize that there are shortfalls to the way that we collect information in the postmarketing period and that there may be problems that are never reported to us, but I think the more important point to us is that one of the requirements in the device amendments is that products be properly manufactured, that they meet performance specifications, and so we do not need the evidence of patient injuries to move ahead and to be motivated to solve this problem.

The public expects, I think, as there have been several comments this morning, that products be well manufactured and that they perform properly, even if the type of performance problem would not have led directly to an injury.

The CHAIRMAN. Dr. Heinrich, could you comment on that question?

Ms. HEINRICH. Yes. Although we have not found any direct evidence of harm, we know that the reporting systems that are in

place are not very good and certainly the reprocessing calls for more science to really inform our decisions. It is interesting that when we looked in a variety of places for some evidence, and you would expect if there were major problems that you would see some clusters of adverse events, and there do not seem to be those. At least there are none reported and the reprocessing has been going on for many years. We still concluded that we need to have better policies and procedures and better oversight.

The CHAIRMAN. Senator Kennedy.

Senator KENNEDY. Thank you. There have been some countries, as I understand, France, and I understand China, as well, that have banned the use of disposable medical devices. Did the GAO look at why these countries banned the practice altogether, Dr. Heinrich?

Ms. HEINRICH. We did not look at the practices in other countries. Certainly in our review of the literature and materials, we saw that Canada had banned them at one time and then reversed their policy. We also noted that there were some instances in Brazil of problems. Those seemed to be related to the quality of the water, but, you know, the specific answer to your question is no, we did not evaluate other countries' experiences.

Senator KENNEDY. I would be interested in just why they did that, why they made that judgment, and whether you think those are good reasons why they did it or not. I do not know whether you can do that or not. Maybe I can talk to the chair and we will see what we might request on it.

Ms. HEINRICH. We certainly could do that.

Senator KENNEDY. Now, as I understand the process that will go ahead, we have tough requirements for manufacturers to demonstrate safety and efficaciousness, that will now be enforced against reprocessors; is that right, Dr. Feigal?

Dr. FEIGAL. Yes, that is.

Senator KENNEDY. What will be included and what will be excluded? What will fall within the category of having to meet these requirements and what will be excluded? Have you gotten that far down the line?

Dr. FEIGAL. Well, in the documents that we posted in February, those mostly dealt with the issue of which types of devices would get our attention first. We intend to phase in this policy for all types of reprocessing of single-use devices. It spreads across the entire range of devices from devices that are exempt from premarket application to us to devices that are high risk and require clinical trials.

The approach in general will be take the same approach with the reprocessed manufacturer as we would with an original equipment manufacturer. If the case can be made to us that an exempt device because it has been reprocessed no longer should be exempt, we will evaluate that on a case-by-case basis.

Senator KENNEDY. So the same standards will be used for reprocessing as would have been used in the initial kinds of approval?

Dr. FEIGAL. Yes, that is correct. It will be determined by the nature of the device.

Senator KENNEDY. Do you have any idea how long that will take to set up the——

Dr. FEIGAL. Well, we announced that we intended to start the clock in July and we still intend to do that. We have not backed off from that at all and we announced an approximately 18 month phase-in period. The reason we were asked to do this is that there were concerns about spot shortages of products if we had a rapidly implemented process. It also is the way we usually do business, which is to start with the highest risk products first, turn our attention to those, and then work our way to the lower risk products.

Senator KENNEDY. Dr. Heinrich, have you found evidence of nonuniform reprocessing practices across hospitals or within the same hospital?

Ms. HEINRICH. We were not able to do a general survey of hospitals in the United States, but people, experts that we talked with in infection control, for example, safety experts, have said that—and we actually saw some hospitals where the practices are exemplary—but we were told that that is not uniform across the United States.

Senator KENNEDY. Are you able to make any assessment as to how many are good or worthwhile and how many are not?

Ms. HEINRICH. No.

Senator KENNEDY. The GAO report points out that little data exists on the safety of single-use devices and the data that is available is of limited value. What kind of data do we need? How long do you think that will take to get?

Ms. HEINRICH. I think that the process that FDA will be putting into place to really identify institutions and third-party organizations that are reprocessing will give us some of that information. I think that it is very clear that there need to be scientific studies that actually evaluate and validate some of the processes for cleaning and also provides a scientific base for standards by which you could test functionality of devices as necessary.

Senator KENNEDY. Just finally—my time is up—what could you tell us as to the nature of the threat to the health of Americans who are using these reused devices? What kind of assessment would you give to the patients today? Is it a remote danger to their health? Is it something more? Is it moderate? Is it for real? What can you tell us?

Dr. FEIGAL. Well, I think one of the things we can look at is what are the kinds of problems we have with products designed for multiple use that the hospitals are already cleaning and reprocessing and putting back into practice, and there we do see from time to time outbreaks of serious infections from devices typically where they are not cleaned properly. So one level of threat is the threat of infection and I think that it will be different for some of these devices because some of the reasons that these are for single-use only is they are difficult to clean because of the nature of their construction.

The other type of threat is from poor performance, and there I think the threat varies with how critical the situation is where the product is being used and what kind of time frame there is to replace it if the product is not used properly. It is different if it is a catheter used inside the body than a pulse oximeter that is clipped on to the finger or the ear and so I think that there is not a single answer to your question, but I think these are the type of

issues that we will be able to address more fully as we begin to get the applications.

Senator KENNEDY. My time is up, Dr. Heinrich, but let me ask you should we then be telling people as part of informed consent that a device has been reprocessed? Just answer that question and then thank you, chairman.

Ms. HEINRICH. I would like to say that the risk of infection is there whether it is new or reused and we certainly could not differentiate between the two. The good news is that the in-hospital infection rates are going down. The bad news there is that a lot of procedures are now being done out of the hospital and we just do not have information on out-of-hospital infection rates.

In terms of the issue of informed consent, you know I think it is really important as a general principle that our patients have as much information about their health, the procedures, as is possible, and we should all encourage that to happen. I do not know that we have evidence that informed consent per se about the use of a particular instrument or device will assure us of the safety that we are all seeking.

The CHAIRMAN. Senator Collins.

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you very much, Mr. Chairman. I want to start by thanking you for holding this hearing which Senator Durbin and I requested that you do and I do have an opening statement that I would like to insert in the record. It was Senator Durbin who first interested me in this issue and I have followed the GAO's report, which I was a co-requester of, with great interest.

To me, this whole issue raises a fundamental question and that is whether it is deceptive for a device to be labeled as single use when, in fact, it is likely to be reprocessed? If it can be safely reprocessed, then the question arises in my mind why is it labeled as single use? And it seems likely that it is labeled that way for marketing reasons.

Similarly, questions occur about whether it is fair to the patient to be charged the price of a single-use new device when, in fact, what is being used on that patient is the device that has been reprocessed? Even if it has been safely reprocessed, essentially it is a used device and the patient is paying as if it were a new device.

[The prepared statement of Senator Collins follows:]

PREPARED STATEMENT OF SENATOR COLLINS

Mr. Chairman, thank you for calling this morning's hearing to examine the public health and safety issues associated with the reprocessing of single-use medical devices.

Over the past several months, considerable concern has been expressed in the media regarding the practice of reprocessing and reusing medical devices that were designed, manufactured and approved by the Food and Drug Administration for use in a single patient, during a single procedure.

Devices that have been labeled by the manufacturer as "single-use" can range from relatively simple implements like surgical saw

blades and drills to technologically complex medical devices such as catheters that are inserted into the heart to monitor cardiac functioning. Proponents claim that only a small percentage of medical devices actually used by hospitals are reprocessed and that the reprocessing of devices labeled as "single-use" has been done safely for more than 20 years, reducing medical waste and generating savings for patients and hospitals alike. Others have expressed alarm, arguing that the practice lacks proper oversight by the FDA and presents patients with an unacceptable risk of infection or device malfunction.

Mr. Chairman, our primary goal should be to protect public health and safety. Like other members of this committee, I am committed to ensuring that all medical devices, including reprocessed medical devices, are safe and effective for their intended use. The GAO will testify this morning about its encouraging new report which finds that certain devices can be reprocessed safely as long as appropriate procedures are followed and closely monitored. It is important to note, however, that the report also finds that some single-use devices cannot be safely reprocessed and that, even for devices that can be reprocessed safely, cleaning and sterilization procedures are not always followed correctly.

The Food and Drug Administration has been criticized in the past for inconsistencies in its regulation of single-use device reprocessing. I am therefore looking forward to hearing about its proposed new regulatory framework that makes major changes intended to strengthen the oversight of single-use device reprocessing.

Again, Mr. Chairman, thank you for convening this hearing, and I look forward to working with the committee on this important issue.

Senator COLLINS. Dr. Heinrich, you noted in your testimony that reprocessing is done because it saves money and it saves hospitals costs at a time when they are under a lot of pressures, but are these savings passed on to the patients or passed on to third-party payers like Medicare or Medicaid?

Ms. HEINRICH. We did not look specifically at how in a systematic fashion about how hospitals in general account for the cost of devices as they are billing. I can tell you that in talking with some hospitals, we found that they have a system in place where they know that they expect to use a particular device five times. So they figure in the original cost, the cost of reprocessing, divide it by the number of times that they expect to use it, and that is what they charge patients. So that they really are passing on the lowered cost.

So I guess the answer is there probably is quite a bit of variability there and we would have to do more work to give you a definitive answer. On the issue of the single-use labeling, I really think that that is very important and we all expect that the FDA labeling will be truthful and will be supported by scientific evidence. And the single- use label we do not have that.

Senator COLLINS. Dr. Feigal, do you have any comments on the issues that I raised about whether it is potentially deceptive, or misleading perhaps is a softer word, if a device is labeled single use

but, in fact, is going to be reused and there are cost savings associated with that, whether those are passed on?

Dr. FEIGAL. I think if the manufacturer intended to promote it for reuse, then, in fact, it would be deceptive labeling, but once the manufacturer sells it, if someone else decides to retrieve the device and remanufacture it, if you will, that is out of the original manufacturer's control.

Senator COLLINS. Do not the manufacturers know that a lot of these devices are likely to be reprocessed?

Dr. FEIGAL. Yeah. Well, in many cases they do, and, in fact, there is one example cited in the GAO report where the manufacturer actually recycles and refurbishes the devices themselves. Now if you notice in that case, though, they were still only used once and then returned to the manufacturer and remanufactured. So, in fact, they were designed to be used once prior to being returned to that manufacturer.

I think the GAO report actually characterizes some of the nuances in terms of how single-use labeling comes about. Some of it is market driven because it is cheaper to prepare an application for approval for a product for single use because you do not have to develop any of the documentation about how to clean the product. And so there are times when the manufacturer probably may not even fully have evaluated whether the product could be reused multiple times and it may be a biggest decision that they are quickest on to the market if they market it as a single use device.

Senator COLLINS. Dr. Heinrich, I have talked to several physicians and emergency room nurses to get their views on this issue and I found very mixed reactions. Some of them thought there was absolutely no problem with using reprocessed devices. Others frankly told me that if they were the one being operated on, they sure would want it to be a new device. Did you interview health care providers as part of your studies to get their views on the safety issue?

Ms. HEINRICH. Yes, we did. We interviewed physicians, nurses, infection control experts, hospital safety experts, to name just a few of the groups that we talked with. And I thought it was very interesting because most of them simply said that they were neutral on the topic or again that they thought that with the proper cleaning and sterilization and testing that certain devices could be done safely.

I think everybody is very cautious and, you know, were not able to make a statement that would generalize this practice. They wanted to be sure that each device was considered separately.

Senator COLLINS. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator. Senator Dodd.

OPENING STATEMENT OF SENATOR DODD

Senator DODD. Thank you very much, and I, too, will ask unanimous consent that a statement, a brief statement, be included in the record.

The CHAIRMAN. It will be.

Senator DODD. And just again, I will State the case. We have all said it before. We are deeply proud of the work the FDA does. FDA approval is really the gold standard not just in this country but

around the world, and so the reprocessing of approved devices is a very important issue, and I am pleased that FDA is taking it seriously and working aggressively to develop some new regulations in this area. I suspect as well that you do because this is an emerging area of technology that there are going to be additional requests for financial assistance for FDA to take on this additional responsibility. So I will get to that in a minute.

I was fascinated by this list in the GAO report of the FDA's list of frequently processed devices. It is really a broad range of devices. Some of them I do not have the vaguest idea what they do, but I know what a catheter is, and what operating room drapes are. I am wondering why some of these devices would be reprocessed at all, a drill, for instance, or biopsy needles. The idea of reusing that sort of device gives me chills, whereas a drape or an operating room gown, presumably there is a good cleaning materials that you can use to wash those things sufficiently so that they would not pose a risk under proper cleaning.

For layman's purposes, I might ask you just to give us some sense of the range of device being reprocessed.

[The prepared statement of Senator Dodd follows:]

PREPARED STATEMENT OF SENATOR DODD

Mr. Chairman: Thank you for convening this hearing on the issue of medical device reprocessing and thank you for joining me and other members of this committee in asking the GAO to look into the patient safety concerns raised by the reuse of medical devices.

The protection offered to the American public by the FDA's stringent safety and effectiveness standards for drugs and medical devices is unparalleled. Tragedies suffered by other nations as a result of unsafe or contaminated products have largely been avoided here as a result of the FDA's vigilance.

Around the world, "FDA-approved" is the gold standard for safety.

However, as we all know, the marketplace for medical products is extraordinarily dynamic—posing a tremendous challenge for FDA regulators charged with ensuring the public safety.

A prime example of the challenge of the changing marketplace is the fairly recent emergence of the medical device reprocessing industry. Just within the past two decades, entities have evolved that can provide hospitals with the option of cleaning, sterilizing, and repackaging single-use medical devices.

While some hospitals have clearly embraced this new practice as a significant cost-saving measure, critical questions about patient safety remain largely unanswered.

If we are going to be able to continue to assure the American people that the medical devices used by their doctors are safe and effective, we are going to have to learn a lot more than we know now about the reprocessing industry. And we are going to have to do a much better job of systematically collecting critical patient safety information.

To start with, we need more reliable data on exactly how common this practice is and the kind of devices that are being reused. And to get a better handle on the impact of this practice on patient

safety, we also need better information on the extent to which reprocessing is linked to infections or device malfunction.

The significant cost-savings that result from reprocessing and reusing medical devices should not be discounted, particularly in light of the recent World Health Organization report revealing that the United States spends more on health care per person than any other country in the world—even though we lag behind other nations in our overall health index.

But, while the cost benefits of reprocessing should be taken into account as we consider our regulatory and legislative options, the economics of the issue should not blind us to potential health risks.

As the agency accountable for the safety of medical devices and medical device reuse, the FDA is in the process of reviewing its regulatory policies for reprocessing, and will announce final guidance within a few weeks.

I applaud the FDA for its responsiveness on this issue, and hope that the new regulations will ensure that reprocessing companies are held to the same high standards that we expect of original device manufacturers.

Again, I thank you, Mr. Chairman, for initiating this hearing. I look forward to the opportunity to hear from a range of professionals and advocates who are familiar with these issues, and hope they can help shed some light for the committee on how best to proceed.

Senator DODD. But let me just get a couple of quick questions in, if I can, Dr. Feigal. First of all, the FDA appears to focus on the initial reuse of the medical device. In other words, I understand the proposed guidelines would require the reprocessor to prove only the device can be reused once. If that is correct, if medical devices are reprocessed more than once, how will safety be ensured beyond that?

Dr. FEIGAL. Well, each time they are beginning with their starting——

Senator DODD. Am I correct? Is it one use? Is it one reuse?

Dr. FEIGAL. Well, they actually could apply for either. There would be a different type of application. If it is for multiple use, they would have to have instructions for cleaning. Presumably that would be a setting where the refurbisher was not going to do the cleaning themselves. But for a device that has been used——

Senator DODD. Let me stop you for a second.

Dr. FEIGAL. Fine.

Senator DODD. There are two kinds of reprocessors. There is the in-house reprocessing.

Dr. FEIGAL. Right.

Senator DODD. But you do not cover them all?

Dr. FEIGAL. No, that will be covered as well. The reprocessing is remanufacturing whether it is a hospital or a third party.

Senator DODD. But presently it is not?

Dr. FEIGAL. Presently we have not been involved in this area.

Senator DODD. So anything done in-house basically we are relying on the hospitals to make a determination?

Dr. FEIGAL. That is right.

Senator DODD. And if it is done outside in one of these reprocessing, you are involved to some extent already?

Dr. FEIGAL. We have begun to be involved in; that is correct.

Senator DODD. All right. Now what is the notion on the question one-time re-use. Are you looking at the possibility of multiple uses or just one additional use? And again we are talking about reuse from drapes to catheters. So I presume the range of risk is pretty diverse.

Dr. FEIGAL. If someone were to bring in an application to us for a multiple-use device that presumably they were going to sell to someone and it would have all the things we would expect of a multiple-use device like instructions for cleaning, how to evaluate whether or not it still functioned adequately, that could come either from original manufacturer or someone who is remanufacturing things from salvaged equipment.

On the other hand, I am sure there will be products where the refurbisher intends each time to release the product once for use before it is again remanufactured. And in that kind of setting, then they will be required to show that they can take as a starting material a used device and remanufacture it to one that will function again adequately, and that will vary by the type of device in terms of how appropriate that is and how long it can be used. It will be different for a steel saw blade than it would be for a plastic catheter.

Senator DODD. A drill, for instance, obviously.

Dr. FEIGAL. Yeah, for a drill bit, for example.

Senator DODD. Do you want to comment on this, Dr. Heinrich? I also wanted to ask you both about the issues underreporting of adverse events. Senator Kennedy and I introduced legislation some time ago to reduce the number of medical errors. In fact, Dr. Frist and the chairman and others have been involved in this issue and concerned about it as well. And the testimony that we are hearing today indicates that there is a substantial lack of information regarding the role reprocessed medical devices play in patient infections and injuries.

In fact, the chairman went into that question in his initial questions to you. Given the current underreporting, the obvious question is will the new FDA proposal contribute to improved surveillance in an area of reprocessed medical devices? And is additional legislation necessary in this area to get proper reporting? I would like to hear from both of you.

Dr. FEIGAL. We already have the authority to actually do a program which we have sought funds for and which we are determined to start one way or another, a program called the MedSun or the Sentinel Hospital Program, where we work with a defined group of hospitals and train them in reporting, and when we did a pilot for that, we found that we got ten times as many reports from that hospital as we would have expected had they been doing voluntary spontaneous reporting.

We think that kind of a system will complement and allow us not just to look at reuse but to look at safety of medical products across the board. So we piloted that program. We have the authority to do it in FDAMA. We intend to move ahead with that program.

Senator DODD. Dr. Heinrich, do you want to comment underreporting?

Ms. HEINRICH. Well, when we reported to you all before on the adverse events when you were looking at medical errors specifically, we said at that time that as we have looked at adverse event reporting, we have not seen that there is a gold standard out there yet, and I think that people are looking at different ways to encourage health care providers to report. I mean we are depending on their voluntarily coming forth saying that there was an adverse event here so that people can go back and really understand why it occurred and take some corrective action.

And I think that there are a lot of issues here. Some people feel that they have to be protected from liability. Some people want to be protected from open public exposure, you know, all these issues I know you are familiar with.

Senator DODD. On this list here, are there some that just should not be reused at all?

Ms. HEINRICH. Yes.

Senator DODD. Which ones? Quickly, I mean in your view? Let us just take them off the list. I mean the drills and things like that, the catheters, why is that being reused at all?

Dr. FEIGAL. Some of these will be a very hard case for someone to make that they can be, but we have never taken the stance that anything was off the table. People can always make us a proposal.

Senator DODD. Is there anything on here that ought to be off entirely?

Dr. FEIGAL. No, I think that our stance historically has been bring us an application and we will evaluate. There are some things I will acknowledge will be very difficult to convince us that they can be used.

The CHAIRMAN. Senator Frist.

Senator DODD. Thank you.

Senator FRIST. Thank you, Mr. Chairman. I will just follow up with what Senator Dodd has initiated, and as a cardiac surgeon, obviously I have used or been in the angioplasty suite or in the operating room when you look at a number of devices like PTCA, which is so routinely used today, the percutaneous transluminal coronary angioplasty, where you are dilating, using balloons to dilate vessels; the EP, the electrophysiology recording catheters; and there are a whole range of devices.

And you mentioned in your written statement, probably mentioned in the oral statement, which I was not present when you made, that May 5-6, FDA and the Association for the Advancement of Medical Instrumentation cosponsored a conference on the practice of reprocessing and reusing SUDs. At that conference, I guess a number of abstracts and papers were presented. Scientists from the FDA's Office of Science and Technology discussed research that they were conducting on the reprocessing of a number of catheters like PTCA and EP catheters.

In May, an abstract of FDA's research, which I have before me here, entitled "The Effects of Use and Simulated Reuse on PTCA Balloons and Catheters," was published by the Society for Biomaterials. And just glancing through the abstract, it reveals that the FDA examined over 400 catheters representing 28 models from eight major manufacturers and found—open quotation here—"cleaning the balloons has proved to be a consistent problem."

Looking on down, the researchers also found that—open quotation—"After over 2 years of technique refinement, we still have some models which are consistently plugged when dried."

There is also evidence in here of the change in functionality of the diameter and flexibility of the balloons which clearly is important if it is your atherosclerotic heart disease that you are having this ballooned; you want it to be perfect. And clearly these devices are not perfect when they have been reused.

There was also evidence in here about the catheters being sticky when you insert these percutaneously. That is why it is called percutaneous, through the skin. That stickiness along the vessel wall affects the ease with which these procedures are performed and safety, I would argue. I guess my concern after looking through this one abstract, and that is the only one that I have looked at—I asked my staff to give me the papers and the complete findings—and I understand that the FDA findings have not been published?

Dr. FEIGAL. Some of them have. They are in the process of going through the peer review literature.

Senator FRIST. With those sorts of findings, I guess I would ask is this expedited? Will you have this sort of data, at least in abstract form, having been released and presented in May? That means the research has gone on for months, if not years. Is the FDA being as forthcoming as it might in terms of presenting that data so that physicians, manufacturers, hospitals, and others have access to that pretty revealing data when you read this abstract?

Dr. FEIGAL. Yeah. We have been presenting that research as it has been developing and that was not the first time that it has been presented. Our goal was to raise in physicians' minds exactly the issues that are in your minds. We cannot comprehensively address all of the issues, but we began by saying what would some of the common problems be and develop some instruments that would assess things like stickiness and that would assess the ability of the balloons to blow up to their intended diameter and so forth.

And we wanted to have a large enough spectrum of products that we could say this is a common problem, these issues need to be addressed and put them on the table. There are many, many more models than those, and it is really up to anyone who wants to reprocess to show that they can address these issues and these issues are just a start.

I think it comes back to Senator Dodd's comment on should these be off the table? You have pointed out these are going to be very, very difficult to show that you can return these to a safe and effective product that performs as we would expect the new one to perform.

On the other hand, some of the other catheters are solid and have different characteristics and have a different history of cleaning and so I think the issues are going to be different, but it was our intent to get this information out.

Senator FRIST. And from your answer, again following up on Senator Dodd's opening line of questioning, the data that I read in abstract form, if I had read the entire study—has the entire study been made available publicly yet to people—that in this particular

abstract, which is an FDA abstract and is pretty condemning, is that data publicly available to everybody at this point?

Dr. FEIGAL. Yes, we can provide the publications that have come forth. There are still others that are in the review process, but we would be happy to provide the committee with a complete set of our publications, both abstracts and full papers and meetings where we have presented the results.

Senator FRIST. I am interested in the publication but also in the data. I am not going to ask you to present data that has not been thought through, but if there are results equal to this in other fields, which, in effect, affect people's safety, I would hope that it is made available as soon as possible. Thank you, Mr. Chairman.

The CHAIRMAN. I am going to go to Senator Reed, then Senator Durbin, then I am going to recess the hearing for about 20 minutes so I will just alert everyone to that. Senator Reed.

Senator REED. Thank you. Senator Durbin has been here.

The CHAIRMAN. But you are a member of the committee.

Senator REED. Oh. And membership has its privileges.

The CHAIRMAN. Absolutely. [Laughter.]

Senator REED. Thank you very much for your testimony today. I would like to ask just a general question. In our society, there are two ways to make people behave—you regulate them or you sue them. You have been looking at the regulations, but I am interested to know if you have also looked at whether there is ongoing and extensive litigation with respect to these products. I would suspect if these devices are really a problem, there would be? Could you please comment on that, or maybe it is peripheral to your activities——

Dr. FEIGAL. I really do not have a very good comprehensive view of that.

Senator REED. Yes, doctor.

Ms. HEINRICH. We actually did talk with hospital risk management companies that would have good knowledge on the issues of litigation and they have not seen it.

Senator REED. OK. Then another question, again a more general question. From what the panelists describe, my sense is there has been quite a shift to the use or reuse of these devices. Is part of that shift a function of the cost of disposal of the devices? Is that a factor that should be considered?

Ms. HEINRICH. Several groups really articulated concern about the volume of exposed materials that have to be disposed of. I know there is a very active group of nurses up in Vermont, as a matter of fact, that have started a whole movement to try to decrease the amount of disposable materials in general that hospitals use because it is a significant problem.

Senator REED. So it cuts both ways in that there are people who are concerned about the sheer volume and would like to see more reusable devices.

Ms. HEINRICH. That is correct.

Senator REED. Then the concern on the other hand is that people might be reusing devices just to avoid disposal costs?

Ms. HEINRICH. Right.

Senator REED. Did your report or does the FDA, consider the cost of disposal as part of the economics of this?

Dr. FEIGAL. Cost really is not our issue, but we are aware that that drives many of these factors.

Senator REED. Let me just ask another question that I think follows the comments made by Senator Dodd and Senator Frist. If these regulations, as the report concludes, are cumbersome, would it make sense to start phasing in the most critical areas of the device framework and then move from there.

Dr. FEIGAL. And, in fact, that is what we have proposed to do. In fact, at the end of the day, when the process is fully implemented, a manufacturer of reused products will be treated the same as the original manufacturer and there is approximately an 18 month phase in period where we start with the highest risk devices and work our way down.

Senator REED. Let me also raise another issue. The FDA has requested that both HCFA and the Joint Commission on Accreditation get involved in overseeing this process. To date, I do not think you have a commitment from—and correct me if I am wrong—from either organization. Can you comment on how vital these commitments are to the success of the proposed framework?

Dr. FEIGAL. Well, I think initially because this is an area we have not been involved before, there is going to be a significant educational component to get people aware of the issues and start working with us on this. And there I think the Joint Commission can be very helpful, particularly because they also regulate any surgery center that has more than two operating rooms, so it is more than even just hospitals. So if we can begin to get in their survey questions questions about reuse, reuse practices, the quality of those practices, I think that will have a very positive effect and we are still in active negotiations with the Joint Commission.

And with HCFA, I think the lever there was thought, well, perhaps there may be some issues around reimbursement. That is a spottier mechanism because many devices are not billed directly. They are imbedded in other costs. So, at this point, we are working most directly with the Joint Commission and we are hopeful that will be a fruitful collaboration. We have also had discussions with the American Hospital Association so I think this is going to be a collaborative effort as we work with a group we have not historically worked very much with.

Senator REED. You might keep us advised as to your progress. And finally, one of the aspects of the framework, is that people/hospitals will register along with other organizations. Do you anticipate a problem with people simply not registering, and what is your plan to ensure that the universe is covered, that you have got everybody in the net?

Dr. FEIGAL. Well, this is actually where the Joint Commission can actually help because they visit virtually all the hospitals. There are some Federal facilities, but that is where these kinds of partnerships are very helpful, because most of the reporting that we have had so far in terms of reuse practices has not been very complete and the advantage of working with the Joint Commission is that they physically visit every hospital, they walk through them, they are there talking to them. So I think that will be one strategy. And the other is just to continue to work through the process. The hospitals that are working with the reprocessors for

some of their products will find out about their responsibilities as they work with the reprocessors. So I think this will take some time to come together, but I think we have a strategy that will bring it together.

Senator REED. From what you have said, it seems then the Joint Commission is a vital part of your proposed plans and should be part of it. Thank you very much. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Collins has agreed to take over for me and come forward. I will depart and recognize Senator Durbin.

Senator DURBIN. Thank you, Mr. Chairman. I thank you for the invitation to be part of your committee and for joining with Senator Collins, myself, and Senator Kennedy in requesting this GAO study. And let me say that in a year we have come a long way on this issue. The first time I raised this issue with the Food and Drug Administration at an Appropriations Committee hearing, they did not detect a problem.

I am glad that they now not only detect the problem but are responding to it. Having said that, let me suggest that the GAO report raises more questions than it answers from my point of view. Let us start at the beginning. The title of the report is "Little Available Evidence of Harm from Reuse, but Oversight Warranted." "Available" is the key word there. Is it not true, doctor, that the FDA when it receives adverse event notices on device use receives about one out of ten actual adverse events?

Dr. FEIGAL. Yes, that is true for devices as well as drugs and other types of voluntary reporting.

Senator DURBIN. And is it not also true that there is no requirement with these adverse events involving devices that there be any notation that it involved a reprocessed device?

Dr. FEIGAL. Well, on the mandatory form, which is over 95 percent of the forms we receive, actually that information is on the form and they are required to fill that out if they know about it.

Senator DURBIN. Mandatory form but not the voluntary form?

Dr. FEIGAL. Yeah, the voluntary form, we get about 3,000 a year. The mandatories we get about 85,000 a year. So of the 85,000, it is on that form.

Senator DURBIN. I am told that on a voluntary form, there is not even a space to note whether it was a reprocessed device?

Dr. FEIGAL. Well, that form is used for drugs and devices and biologics. In the instructions it indicates that you should note if it is reprocessed and it tells you where to put it, but that form is shorter than the mandatory form and it is hard to find space or data items to give up to add that as a device since that form is only used 3,000 times a year for us, and many, many more thousand times for drugs and other products.

Senator DURBIN. Dr. Heinrich, since we are dealing with a situation here where 90 percent of the bad experiences with medical devices are not reported to the FDA, I think it is kind of difficult to conclude that we are in safe territory here, we need not be worried about the harm from reuse. As far as I am concerned, the jury is still out. We just do not have the information about reprocessed devices and the harm that they are causing. Is that true? Would you agree with that?

Ms. HEINRICH. Well, we certainly agree that we have to have better data and all we are saying in our report is that when we looked in a variety of places for documentation that there is a problem, we were unable to find it. And certainly when others have looked, they have not been able to find it. And we really did try to go systematically through the literature, through the FDA data, through information from CDC, from hospital infection control experts. We looked at the ECRI data and they have been collecting data since 1976. I just wanted you to know that we tried very hard to find the problem.

Senator DURBIN. No, I do not doubt your conscientious effort, but I think your use of the word "available evidence" really tells the story. There is just not much evidence available.

Second, let us get to the heart of this. Why do companies sell single-use devices? I think there are three reasons. One is obvious. Profit. If you can sell a number of devices as opposed to one that is going to be reused, you make more profit. Second is the Federal court case, which you noticed in your GAO report, the judge said, well, they are manufacturing these devices to the performance requirements of the FDA. And the performance requirements for a single-use device cannot be nearly as demanding as one for a multiple-use device. And so they start off with the premise that they do not have to manufacture to that high standard of reuse.

And the third is to absolve themselves from liability. If ultimately someone is sued for reusing a device that causes a problem, the manufacturer can say wait a minute, it was a single-use device, clearly labeled, leave me out of this discussion. I think that is what is behind this in terms of the manufacturer's decision. But the point that really gets to the question here which I think should have been raised more effectively by the GAO is when a single-use device manufacturer sends instructions on how to sterilize and reuse the product along with it. Is that not a clear deception? This is not a single-use device if they anticipate that it is going to be reused and even give manufacturers directions of how to reprocess it and sterilize it? Does that not raise a question in your mind about deception? Anybody? Anybody?

Ms. HEINRICH. Well, as I said in answer to Senator Collins' question, I think that we all want the FDA labeling to be based on scientific data and the way that the regulations have evolved, we have not required the same kind of scientific evidence for single-use labels.

Senator DURBIN. Well, I think this GAO report is going to be looked back in years to come; they are going to look back on it and say they were just scratching the surface.

Ms. HEINRICH. The surface.

Senator DURBIN. They really did not get into the issue here. I think my point of view is if I am a patient in a hospital and some doctor wants to use a medical device on me in the course of a surgery that was a single-use device and has been reprocessed, I think that should be noted on my chart so that if something goes wrong, it can be reported to the FDA, and I think I have the right to consent to that.

If they want to use an original equipment single-use device, that is what I anticipate when I go to the hospital. I do not anticipate

that it has been used a dozen times and it might have in reprocessing not been sterilized adequately.

I am sorry that at this panel today there is not a single representative of a consumer or patient. I think there should have been because I think there is another side to this story. Thank you.

Senator COLLINS. [Presiding.] I want to thank our witnesses and I will now call forward the second panel. On our next panel we welcome Josephine Torrente, the president of the Association of Disposable Device Manufacturers. She is also an FDA attorney at the law firm of Hyman, Phelps & McNamara in Washington, DC. In addition to her law degree, Ms. Torrente has earned both a bachelor's of science and a master's of science in biomedical engineering, specializing in biomaterials and biomechanics.

Also, on this panel will be Vern Feltner, representing the Association of Medical Device Reprocessors. Mr. Feltner's distinguished career includes service as president of Searle Medical Specialties and president of Marquest Medical Products. Currently, Mr. Feltner serves as president of Alliance Medical Corporation and is a frequent speaker on the topic of reprocessing medical devices.

Next, we will hear from Dr. John Clough on behalf of the American Hospital Association. Dr. Clough is currently director of Health Affairs for the Cleveland Clinic, a position he has held since 1991. Prior to that, Dr. Clough headed the Cleveland Clinic Special Immunology Laboratory from 1972 until 1990. He is also editor-in-chief of The Cleveland Clinic Journal of Medicine and a member of the Cleveland Clinic Foundation Board of Trustees. Dr. Clough also serves on the American Cancer Society Board of Directors and the United Cerebral Palsy Board of Directors.

As our final witness on this panel, we will hear from Anne Cofiell on behalf of the International Association of Healthcare Central Service Material Management. She currently manages Cofiell Consulting Services specializing in the areas of decontamination, sterilization, supply, processing, and distribution management, central service policies, and procedures, recommended practices and regulatory issues affecting central service.

I want to welcome all of our witnesses here today and Ms. Torrente, we will start with you.

STATEMENTS OF JOSEPHINE M. TORRENTE M.S., J.D., PRESIDENT, ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS, WASHINGTON, DC.; JOHN CLOUGH, M.D., ON BEHALF OF THE AMERICAN HOSPITAL ASSOCIATION, CHAIR, DIVISION FOR HEALTH AFFAIRS, CLEVELAND CLINIC, CLEVELAND, OH; VERN FELTNER, ON BEHALF OF THE ASSOCIATION OF MEDICAL DEVICE REPROCESSORS, PRESIDENT, ALLIANCE MEDICAL CORPORATION, ASHEVILLE, NC; AND ANNE COFIELL, INTERNATIONAL ASSOCIATION OF HEALTHCARE CENTRAL SERVICE MATERIAL MANAGEMENT, MT. LAUREL, NJ

Ms. TORRENTE. Thank you, Senator Collins, and thank you to the committee for the opportunity to address this important patient safety issue. Contaminated and malfunctioning reprocessed single-use devices are at a minimum potential medical errors. They are more likely patient injuries, misdiagnoses and cross-contaminations

with infectious agents. Over 1,200 reprocessed devices have been pulled from hospital shelves where they were awaiting use in patients.

These devices include catheters, staplers, trocars, and orthopedic devices. You would be horrified at the results. Over 75 percent of these devices were found to be contaminated, not sterile or defective. These are devices that were awaiting use in patients. I want to show you what a single-use device looks like in its sterile packaging. This is a biopsy forceps. It is 240 centimeters long. This device is used to insert into the colon and take small samples of tissue for cancer screening of the intestine. My associate is putting up a picture of the internal intricate workings of that device. It is not hard to imagine the types of patient material that this device gets contaminated with and how harsh cleaning and sterilization practices can damage these delicate components. It is perhaps because of this complexity that GAO found reprocessing is not invariably safe.

The next picture shows rust and debris left behind on a similar biopsy forceps after reprocessing. If this device had not been selected for testing, it would have been used in the next patient exposing him to potential injury or infection. Unfortunately, this result is not unexpected. Our testing predicts that nearly 50 percent of reprocessed single-use biopsy forceps sitting on hospital shelves today are contaminated.

In comparison, new devices must meet the requirement of no more than one in one million nonsterile. This is the standard that manufacturers are held to. This is the standard that protects U.S. patients. It is the standard that is ignored by the reprocessing industry. The statistic is actually laughable. Reprocessed products being used in patients today are 500,000 times more likely to be contaminated than devices recalled by manufacturers. Think about that. Manufacturers prophylactically recall products 500,000 times less likely to infect a patient.

FDA is not protecting the patients here. And the patients are not being given the information to protect themselves. Despite these data, proponents of reprocessing continually tout the lack of actual injury reports as evidence that reprocessing is safe. What this really is is evidence that no one is looking. GAO found that current monitoring does not capture all patient injury data for a variety of reasons. First and foremost, reprocessing, as Forbes magazine said, is medicine's dirty little secret, more often covered up than acknowledged.

In the audience today is a woman named Georgia Abernathy. Ms. Abernathy's mother suffered a serious injury when a reprocessed device fractured during her mother's procedure. It was supposed to be there to extract a kidney stone, but due to excessive fatigue the advice failed inside the patient.

Ms. Abernathy works in the medical device industry and so was aware of reprocessing, unlike most patients and their families. Despite her awareness, it took intensive investigation for her to find out that the device used on her mother had been reprocessed. Four months later this injury has still not been reported to the FDA. No wonder the safety record of reprocessing looks so exemplary when

no one is reporting. The reality is patients are being injured and they will continue to be injured even under FDA's new scheme.

FDA's guidance documents are a step in the right direction. But they are fundamentally flawed. While they require full compliance with the medical device amendments for some devices, the guidance documents leave two enormous gaps in patient protection. They allow some high risk devices to be reprocessed without FDA approval. They also stamp "FDA approved" on products that are not safe for use in multiple patients, as Senator Dodd had alluded to.

Let us look at biopsy forceps as an example. Years ago an FDA expert panel determined that new biopsy forceps are sufficiently safe so that FDA clearance is not necessary. These experts looked at the device and what it is intended to be used for. In deciding there was not a need for safety data, they never considered that people would be taking a device designed for one use and reusing it again and again in multiple patients.

Despite this, FDA intends to extend this exemption blindly to the reprocessing of these devices without foundation in law or science. In fact, FDA's plan appears aimed at nothing more than cutting an enormous corner and limiting FDA oversight of reprocessing. The plan fails to adequately regulate many products including the kidney stone basket that failed in Ms. Abernathy's mother. If FDA executes its strategy, that device failure can happen again.

The second gap in patient protection in the FDA guidance documents is the one Senator Dodd alluded to: reprocessed devices could be sold after the reprocessor shows the device could be cleaned just one time. Who are we kidding? We all know that the reprocessors intend to clean each device again and again. They even supply collection buckets to the hospitals to return the same devices over and over.

Safety data on one cleaning may protect the second patient but it fails to protect the third and the fourth and the 20th. Manufacturers who intend to sell devices for use in multiple patients must show that the devices are safe and effective for the requisite number of uses. This is the right standard for patient protection. FDA should not be allowed to blind itself to the reality of reprocessing. The agency must require data that protects even the last patient on whom these devices are used. Unless these two gaps in patient protection are closed, reprocessing will continue to present an unacceptable level of risk to patients.

FDA is falling behind the rest of the world on this issue. Many European countries have banned reprocessing and 2 months ago even China outlawed the practice to protect its citizens. We look forward to the committees' continued oversight while FDA finalizes its policies. The draft guidances must be changed. Otherwise, we would be better off leaving this illegal than putting an imprimatur on it that gives false comfort to patients and health care workers. Thank you. I look forward to answering any questions.

Senator COLLINS. Thank you for your testimony.

[The prepared statement of Ms. Torrente follows:]

PREPARED STATEMENT OF JOSEPHINE M. TORRENTE, M.S., J.D.

Good morning Mr. Chairman and members of the Committee. Thank you for the opportunity to address the Committee on this important patient health and safety issue. My name is Josephine Torrente and I am President of the Association of Disposable Device Manufacturers. ADDM is a trade association of device manufacturers committed to patient safety through tightened FDA regulation of single patient use medical device reprocessing. In addition to practicing FDA law at the law firm of Hyman, Phelps & McNamara, P.C. here in Washington, DC, I have earned both undergraduate and graduate degrees in biomedical engineering, and have conducted scientific research in the fields of biomaterials and biomechanics.

Reuse of disposable medical devices is a practice that has steadily increased over the past two decades despite the numerous ethical, legal, regulatory and, most importantly, patient safety issues it raises. In the past two years, hundreds of reprocessed devices taken from hospital stocks have been shown to be non-sterile or malfunctioning and thus unacceptable for use in patients. Yet, the fact that we have not had hundreds of reports of actual patient injuries due to reprocessing is often touted as evidence that reprocessing is safe. The lack of substantial numbers of injury reports is only evidence that current systems are ineffective in linking injuries to reprocessing. Injury reports are infrequent because reuse, by its very nature, is a stealthy, difficult to monitor practice with physicians and patients often unaware of its existence. Victims of reprocessing are rarely identifiable because (1) the fact that the failed device was reprocessed is rarely revealed and the injury is erroneously attributed to a new device and (2) infections are not easily traced back to the device and are documented merely as a "nosocomial infection" with no reported cause. In fact, a nurse at one Florida hospital reported that the hospital reprocesses single use devices until they break. Once they break, the hospital telephones the original manufacturer to complain about the device failure and obtain a new device. Reprocessing is never mentioned.

Many single use medical devices represent significant advances in medical science with enormous potential benefit to patients. Reprocessing undercuts these advances by exposing patients to non-sterile and malfunctioning products. Due to the innovation of medical device manufacturers, a patient with clogged coronary arteries does not have to endure the trauma of a double or triple bypass operation. Instead, he can undergo a minimally invasive coronary angioplasty procedure and have a tiny, intricate balloon catheter inserted through a small incision in his groin. The catheter is then snaked through his body into the arteries of his heart where it can restore normal blood flow. Under FDA's current level of reprocessing oversight, however, that delicate balloon catheter, manufactured to exacting specifications and not designed to withstand the abuses of reprocessing, may have been previously used on a patient with any number of infections, including hepatitis, and may have undergone unsuccessful cleaning and sterilization at the hands of a third party.

Medical device innovators have also developed devices that allow removal of kidney stones without requiring the patient to endure a long open procedure. A complex, delicate stone retrieval basket can be collapsed into a small space and inserted into the patient through the ureter. The basket is then opened to capture the stone and is collapsed again for removal from the patient. Under FDA's current level of reprocessing oversight, a reprocessor, unfamiliar with the key design characteristics of the device, may attempt to clean a used stone retrieval basket, altering its mechanical properties. The device may then fail to collapse after capturing the stone and thus prevent safe extraction of both the stone and the basket from the patient. To avoid perforating tissue on extraction, the physician's only recourse at that point is to perform an otherwise unnecessary emergency open procedure. Events like these have happened, but because of the structure of the current adverse event reporting system and a lack of accountability on the part of reprocessors, these events are often reported as failures of a new, not reprocessed, device. The clinical failure of reprocessed devices is no surprise. In studies covering over 1,200 reprocessed devices sitting on hospital shelves and awaiting use in patients, over 75 percent of the device were demonstrated to be unacceptable for use in patients.

Despite the clear potential for patient injury and the obvious limitations on current surveillance systems, FDA has chosen not to fully enforce the Medical Device Amendments of 1976 on reprocessors of single use medical devices. Even the FDA's recent draft guidances are riddled with loopholes that will permit unsafe devices to be used on multiple patients. FDA's inaction to date has served as tacit acceptance of this practice and has jeopardized the safety of the very patients the agency was established to protect. Its draft guidances compound the problem by continuing to allow reprocessed devices to be used in multiple patients without supporting safety data.

After providing a brief background on the history and design of single use medical devices, my testimony will focus on three areas: (1) the jeopardy that reprocessing poses to patients, (2) the role of FDA in protecting patients from unsafe and ineffective medical devices, and (3) the gaping loopholes which perpetuate these issues in FDA's new strategy.

History and Design of Single Use Devices

History of Single-Use Devices

Single use medical devices were initially designed in response to demands from the medical community for devices that could be made economically enough to be disposed of after use on a single patient, thereby decreasing the risk of infection in hospitals. The medical community welcomed the advent of one-time use devices as the wave of the future. These innovative devices saved space, were lightweight and eliminated breakage. They also functioned better for both patient and clinician. For instance, plastic intravenous catheters were more flexible and comfortable than needles and greatly reduced trauma to the patient.

Single-use devices have also been key to developing more efficient, less invasive procedures that shorten hospital stays or replace hospital stays with out-patient procedures. As plastic technology improved, devices became smaller, more intricate, more reliable in design and more effective. Moreover, the last ten years have seen the development of hydrophilic surface coatings which have a slippery quality that allow catheters to move easily through the vascular system and into different vessels. Without these coatings, which are heat-sensitive and thus cannot be resterilized, as well as other advances, physicians would be unable to perform many procedures taken for granted today. For instance,

- Angioplasty itself. and in particular the balloon angioplasty catheter, would not have been developed without single-use device technology;
- Critical surgical procedures like bone marrow transplants, hip and knee replacements and open-heart surgery are much safer because of the advent of single-use devices,
- Controlled radial expansion balloons, which dilate esophageal strictures, can only be made for single use; and,
- The repair of brain aneurysms is only possible because single-use device technology gives surgeons the tools they need to reach areas of the brain not previously accessible.

Many of the interventional technologies that have revolutionized medicine rely on the miniaturization, electronics, physical and mechanical design unique to single-use devices.

Design Considerations

To understand the design characteristics of single-use devices, it is useful to consider the criteria a device must meet to be safe for use in multiple patients, and the limitations on single use device design that prevent meeting those criteria. A reusable device must be capable of thorough cleaning and sterilization in both design and materials. Most reusable devices are easily disassembled, have smooth surfaces and are made of durable materials, such as stainless steel. Conversely, a single-use device is designed for optimal performance rather than ease of cleaning, and may be seriously compromised or destroyed by sterilization. The design features of single-use devices typically contain many areas that are difficult to access, such as long, narrow lumens, acute angles, crevices, coils and joints, reinforcing meshes and rough, porous or occluded surfaces. These inaccessible areas create barriers to cleaning and allow for the collection of organic matter, such as blood, feces, urine, respiratory secretions and gastric mucin.

In addition to impaired sterility, single use devices can be functionally compromised by reprocessing. For a device to be considered safe for multiple use, functional performance must be restored to original specifications after reprocessing. To reduce the invasiveness of procedures, single use devices are often designed to be very small, very long, and flexible, yet also maneuverable. In addition, to meet procedural requirements and the performance demands of physicians, original devices are developed over a period of time and include complex assemblies of precision components and carefully selected materials. Many devices carry electrodes, electronic components, and electrical wires, and many devices include complex functional mechanisms. For example, single use biopsy forceps may be as long as 240cm. composed of multiple soft plastic tubes, a metal coil, a steering mechanism, an opening/closing mechanism, and precisely manufactured, sharp biopsy jaws. In addition, "hot" biopsy forceps also carry electrical wires and electrical connections. Electrophysiology catheters are also very long and carry multiple electrodes, multiple electrode wires, two temperature sensors per electrode, two electrical wires per temperature sensor, a complex bi-directional steering mechanism, and radiopaque markers. The assembly process for electrophysiology catheters and the adhesives

and plastics used in electrophysiology catheters are designed to provide a smooth outer surface. Imperfections introduced by reprocessing may allow blood to pool and clot.. resulting in embolus forination. Emboli can lead to serious or fatal injuries such as stroke.

Cleaning and sterilizing a used single use medical device involves repeated exposure to chemical agents and exposure to elevated temperatures or pressures which may damage the device and may cause the device to fail in the next patient. Reprocessing may seriously affect such single-use device properties as sharpness, material strength, flexibility, dimensions, lubricants, tensile strength, burst pressure, leak pressure, surface finish and membrane integrity.

Finally, materials from which single use devices are manufactured may absorb cleaning chemicals causing a pyrogenic reaction in the next patient. Scrubbing may scratch a device leaving a crevice in which material may gather and lead to cross-contamination or a pyrogenic reaction in the next patient. Scrubbing, wiping, rinsing, drying and sterilization may also weaken the device's materials. For example, the insulation on electrical components may wear through and expose live electrical wires to the next patient, or the adhesives maintaining connections between components may weaken and allow blood, other body fluids, or cleaning chemicals to flow into normally unexposed device lumens. Weakened adhesives may also allow device components to separate while the device is in the next patient.

Reprocessing does nothing more than exploit the patient safety margins built into single use devices. As part of the physical testing required for approval of a balloon angioplasty catheter, the manufacturer must test "balloon fatigue" and determine the repeatability of successful balloon inflation to the rated burst pressure. Results must demonstrate that 95% of balloons will sustain forty repeated inflations. These forty inflations provide a safety margin necessary to ensure that each balloon will not sustain a loss of.pressure during a single procedure in which the balloon may be inflated a small number of times. Each reprocessing test and reuse merely degrades that safety margin and brings the device one inflation closer to failure.

Reprocessing Single-Use Devices Jeopardizes Patient Safety

Analysis of Reprocessed Devices

Perhaps the best indication that single use devices cannot be safely reprocessed are the results of studies conducted on reprocessed single use devices.taken from hospital shelves. These studies show that an overwhelming number of tested reprocessed single use devices are either non-sterile or that the devices' functionality has been compromised. Thus there are two general categories of injuries that may result from using a reprocessed single use device: injury from cross-contamination or infection and injury from device failure.

ADDM and its member companies have submitted nineteen abstracts to FDA verifying the existence of valid scientific data confirming the physical, microbiological and functional performance failures associated with reuse of disposable medical devices. This scientific data has been supported by results of studies conducted in the Center for Devices and Radiological Health's (CDR.H) Office of Science and Technology (OST), by independent hospital studies submitted to FDA, by published literature reports and by actual patient injuries and device malfunctions reported to FDA through the MedWatch system.

In total, twenty-five scientific studies involving well over 1200 individual devices have been performed to evaluate reprocessing. Many of the devices used in these studies were obtained directly from hospital shelves where they were "ready for use" in seriously ill patients. Devices studied included biopsy forceps, angioplasty balloon catheters, electrophysiology catheters, arthroscopic blades, surgical trocars, staplers, papillotomes, orthopedic devices and other general surgical instruments. The majority of these devices failed testing, either due to the presence of blood and/or proteinaceous matter, bacterial contamination, non-functionality, or defective packaging. In each of seven studies of reprocessed biopsy forceps, a lack of sterility assurance was reported in over 45 percent of the samples tested. This particular failure was not unexpected. As recently as last October, FDA issued a warning letter to one of the largest commercial third-party reprocessors specifically citing the reprocessor's failure to adequately validate the sterilization process. These studies also found devices with mismatched parts. a high frequency scalpel blade designed to be blunt that was, instead, sharpened, a surgical stapler contaminated by a large piece of proteinaceous matter, and devices lacking warnings about latex content. These twenty-five separate studies clearly demonstrate that reprocessing a single use device may seriously compromise the integrity and subsequent safety and efficacy of that device.

These studies can not be dismissed as providing only "theoretical" evidence of the risks of reprocessing. Manufacturers often recall devices and have product seized on the basis of less egregious findings. For instance, in March of this year Clinipad Corporation recalled products due to confirmation of microbial contamination in

some lots and the resultant inability to assure the sterility of products labeled as sterile. It is important to note that the recall was initiated -despite a lack of confirmed reports of patient complaints or injuries resulting from these products.

Patient Injury Reports

In addition to the laboratory data discussed above, at least nine reports of actual patient injuries have implicated reprocessed single use devices. In one instance, the distal tip of an electrophysiology catheter separated from the body of the catheter while the device was inside a patient's heart. The tip did not break completely free of the catheter due to a safety wire connected to the tip. The hospital acknowledged reusing the device and further analysis revealed a bond failure most likely due to aggressive disinfecting and cleaning between uses. Testing demonstrated that there was a jagged separation at the bond due to a force believed to be applied during repeated cleaning. Another reprocessed electrophysiology catheter tip fractured leaving a piece of metal lodged in the patient's heart.

In a similar incident a loss of vision was caused by a reprocessed cardiac catheter, the tip of which fragmented and lodged in the patient's central retinal artery on the optic nerve head of the patient's right eye. leaving that eye with only light perception vision. At the end of a six-month follow-up, the patient's right eye vision remained only perception and nasal projection of light. The catheter fragmentation was attributed to the resterilization process and the reuse of the single-use device. Another patient suffered loss of vision in one eye due to use of a reprocessed phacoemulsification tip during cataract surgery.

One patient who underwent bilateral foot surgery suffered peritonitis after a reprocessed aluminum intubation stylet broke in the esophagus and perforated the duodenum. Similarly, a portion of a reprocessed esophageal stethoscope broke off in a patient's oral airway during thoracotomy causing a potential airway hazard. Failure to adequately reprocess a disposable pulse-oximeter sensor led to bums on the foot of a premature infant exposed to the unshielded metal of the device.

Increased infection rates have also been reported. In one instance a hospital traced 25 cases of a specific strain of bacteremia over a four and one half month period to reprocessed disposable pressure transducer domes. No further cases were recognized once the hospital stopped reprocessing the domes. Finally, in another study, approximately 60 percent of pediatric patients on whom reprocessed tracheostomy tubes were used developed pneumonia within the previous year, compared to only 25 percent of pediatric patients on whom new tracheostomy tubes were used in the same time period. Other potential variables such as patient age, diagnosis, method of tube cleaning, and frequency of tube change showed no correlation to increased incidence of pneumonia, leaving tracheostomy tube reuse as the only predictor of pneumonia.

Masking the Evidence

In an attempt to provide evidence of the safety of reprocessing, the reprocessing industry often cites the small number of adverse event reports in FDA's Medical Device Reporting (MDR) database for reprocessed single use devices. This mischaracterizes of the truth about reprocessing and creates a false sense of security for health care professionals and the public.

Adverse events associated with the use of reprocessed single use devices are underreported. This underreporting occurs for three principle reasons. First, a reprocessed device continues to carry the name of the original device manufacturer, not the reprocessor. Thus, safety reports are likely attributed to, and reported to, the original manufacturer of the device rather than to the reprocessor, and are not traced back to the reprocessing. The second factor leading to underreporting of adverse events associated with reprocessed single use medical devices is the difficulty in tracking the cause of many nosocomial infections. Finally, additional underreporting occurs due to the healthcare workers' fears of potential liability resulting from use of a reprocessed single use device against the manufacturer's express warning and without the informed consent of the patient.

Due to the failure of reprocessors to replace the original manufacturers' names on reprocessed devices with their own names, adverse events which occur with reprocessed devices are often reported to the original manufacturer rather than the reprocessor. The OEM is then obligated to report these to FDA as a failure of a new device. There is thus no way to discern how many device failures in FDA's MDR database are actually for reprocessed rather than new devices. Discounting reprocessed device failures by noting that the MDR system contains a similar report for a new device fails to recognize that that MDR report may have also been for a reprocessed device. It also fails to recognize that the device performed without failure the first time it was used. Had it been discarded after the first use, the failure would not have even occurred.

The ability to link an infection or pyrogenic reaction to the residues on reused single use devices is difficult if not impossible. Usage in the patient will itself reduce the evidence remaining on the device. Further, the devices will often already have been discarded or reprocessed again before the injury is discovered, and particular device usage on each patient is not tracked. Identifying the infectious source is generally very difficult because the infectious status of most patients is unknown, there are a large number of patients having similar procedures, and the particular devices used on each patient are not tracked. Of further note, after single use devices are used, the hospital must immediately clean the devices and then keep them in a wet environment/bath until the devices can be transferred to a commercial reprocessor. The wet bath will likely include multiple devices which have been used on different patients. Consequently, if any of the devices are contaminated they may share this contamination with the other devices in the wet bath, making it more difficult to prove cross-contamination.

By way of example, one ADDM member reports that. in May 1997, a patient tested positive for hepatitis B after a biopsy procedure was performed at a Texas hospital. A single use biopsy forceps was used in this procedure as well as a reusable endoscope. The hospital had a contract with a commercial reprocessor to reprocess single use only biopsy forceps, and the original manufacturer's sales representative learned from hospital staff that the biopsy forceps might have been reused. When the sales representative notified the hospital that an MDR would have to be filed, the hospital stopped all communication regarding this issue. The hospital did not return the device to the manufacturer, and the hospital would not state whether the device had been reused. Approximately I week later, the hospital canceled its reprocessing contract. The hospital did not file an MDR. In this instance, the manufacturer became aware of the situation only by having a representative in the hospital around the time of the incident. As a result, an MDR form was filed by the manufacturer, but the form is inconclusive at best. It is impossible to know how many similar incidents go unreported.

Another difficulty in tracking injuries caused by reprocessed single use devices is that the hospital is not required to report whether the failed device was reprocessed. Section H(8) of FDA's MedWatch form is entitled "Usage of device" and includes the following choices: 1) initial use of device, 2) reuse or 3) unknown. Section H, however, is to be filled out by the "Device manufacturer only." As a result, reuse of devices is again under-reported because the hospital, who is in the best position to know whether the device has been reused, is not required to identify whether the device was in fact reused.

Lack of analysis on failed devices also leads to under-reporting of injuries due to use of reprocessed single use devices. Failed devices are rarely returned to the manufacturer for testing or evaluation. Consequently, the device cannot be tested for cleaning chemicals or other signs of reprocessing. Where failed devices have been returned, however, some have shown signs of reprocessing. These signs include evidence of cleaning/scrubbing, such as abrasions and jagged break points, and evidence of cleaning chemicals which are not used in the original device manufacturer's manufacturing facilities. In one instance, a failed electrophysiology catheter was returned to the manufacturer. Analysis revealed the presence of high levels of chlorine, possibly due to the use of bleach. This agreed with visual findings of corrosive failure as the tip material is sensitive to extreme pH levels. The tests have been strong indications of reprocessing but have not provided conclusive proof Accordingly, original device manufacturers indicate "unknown" in Section H (8), and failures due to reprocessing continue to be under-reported.

Proponents of reuse often discount patient injuries noting that the device failure cannot be definitively linked to the reprocessing. All failures associated with reprocessed used single use devices are directly attributable to reuse. If the device is being used a second, third or sixth time, the device must have functioned properly the first time - as intended. If the device had been used once and discarded, in accordance with its labeling, it would not have failed. Exhaustion of the device's safety margins by reprocessing will cause the device to fail, perhaps by a failure mode that has also occurred with new devices. This overlap in failure modes does not change the cause of the failure in the reprocessed device.

FDA Must Protect Patients from Unsafe Medical Devices

The Medical Device Amendments of 1976 were enacted for the purpose of implementing pre-market review of devices because Congress was concerned that post-marketing regulation of medical devices was inadequate to protect the public health. The Amendments require that, prior to their introduction into interstate commerce, all medical devices must be FDA-cleared or approved through the prernarket notification (5 1 0(k)) or prernarket approval (PMA) process. This process requires submission of data by the party that intends to market the device. For a single use

device, the OEM demonstrates that the device is safe and effective for use on a single patient in a single procedure. and the device is then cleared/approved for only that use.

Premarket notification is also required to be submitted by a manufacturer who significantly changes or modifies the intended use of a product. "Intended use" is defined as the "objective intent of the persons legally responsible for labeling a device."[1] Thus, the original device manufacturer's objective intent typically determines the intended use of a device. A 64single use" or "disposable" designation on a device label constitutes highly objective evidence of the manufacturer's intent regarding how the device should be used.

FDA is in apparent agreement with this position as it relates to original device manufacturers. In order to change the labeling, and thus the intended use, of a device from single use" to "reusable," such a manufacturer must submit a 510(k) application containing data which demonstrates that the materials used can withstand the rigors of reuse.. that the device design allows easy cleaning, and that the cleaning and sterilization methods have been validated. The 510(k) must also include data to show the maximum number of times the device can be reused. By requiring this data, the Agency has indicated its position that post-approval inspections and other regulations alone are insufficient to ensure the safety of a device whose intended use is altered in this way. According to the Agency, however, no such data has been required from a commercial reprocessor who similarly chooses to change a device's intended use from "single use" to "reusable." The result is that a reprocessor may market Manufacturer X's device for use in multiple patients, while Manufacturer X may only market it for use in one patient.

FDA recognizes that reprocessors of single use devices are manufacturers under the FDC Act and its implementing regulations, and, as such, reprocessors are subject to the provisions of the FDC Act that require manufacturers to obtain clearance of a 510(k) or Approval of a PMA. Despite this recognition, FDA has permitted reprocessed single use devices to be marketed without its prior clearance/approval, and, to date, has subjected them only to limited and disappointing post-market regulation. This unjustifiable use of enforcement is not supported by the law or by sound public policy. Waiting for substantial numbers of patient injury reports before regulating reprocessors ignores the importance and rationale for the FDA's entire premarketing system that is designed to ensure patient safety, and the fact that to date, these patient protections do not exist for reprocessed devices.

All parties (FDA, hospitals, reprocessors and OEMs) agree that there are at least some devices which absolutely cannot be reprocessed safely, but there is currently no barrier to placing these devices on the market. For instance, many experts, including some third party reprocessors, agree that balloon angioplasty catheters cannot be reprocessed. Despite this, the largest third party reprocessor in the country currently reprocesses these devices for hospitals to use in patients.

Rather than fully enforce the regulations, FDA has discussed developing voluntary standards for reprocessors. The enforcement of existing regulations, rather than the creation of voluntary standards, is the congressionally mandated solution to the issues surrounding reprocessing of used single use devices. In the economic world of commercial reprocessing, voluntary standards, with their lack of an outside referee, are inadequate to ensure that devices incapable of being reprocessed are disposed of Contrast this laissez-faire approach with the new law in China that bans reuse outright and has provided for systems to monitor compliance with the ban. Similar laws protect patients in other countries from reprocessed devices. In the US, however, patients are unprotected and are not given the information necessary to protect themselves.

Significant Loopholes Render FDA's New Guidance Documents Ineffective

Guidance Document Overview

In February 2000, just two days prior to a hearing before the House Commerce Committee Oversight and Investigations Subcommittee on the FDA's regulation of reprocessed single use devices, FDA released two draft guidance documents, which, if finalized, could require reprocessors of some single use devices to fulfill substantially the same premarket submission requirements as original manufacturers of single use devices. While the two draft guidance documents represent a step forward in the enforcement of the Federal Food, Drug, and Cosmetic Act on some reprocessors, they present new concerns that compound the problems of non-enforcement of the Federal Food, Drug, and Cosmetic Act on reprocessors of single use devices. Specifically, FDA's new strategy (1) presents new risks to patient health and perpetuates the regulatory inequity between reprocessors and original manufacturers by

[1] Id. Sec. 801.4.

exempting reprocessors from fulfilling premarket requirements for certain devices; and (2) continues to frustrate the letter and spirit of the 1976 Medical Device Amendments by allowing reprocessors to sidestep the most critical data elements needed to show safety and effectiveness of a device for use on multiple patients.

In today's world of increasingly complex medical devices and heightened concern over disease transmission, the significant loopholes in FDA's new strategy are inconsistent with Congress' intent. In enacting the MDA, Congress' goal was to protect patients from unsafe and ineffective devices, regardless of the identity of the device's manufacturer. As such, there is no justification for a patient to receive less protection from FDA merely because the device used for the patient's treatment is a reprocessed single use device rather than an FDA-cleared reusable device.

FDA's Plan to "Exempt" Devices

FDA's draft guidance documents reveal a plan to exempt certain devices from the premarket requirements with no solid foundation in law or science. Products will be exempted merely because the device is considered to have a reasonable assurance of safety for one use or because a comparable device which was designed for reuse exists. FDA has already noted that this loophole allows reprocessing of several devices which FDA actually believes present a high risk to patients once reprocessed. While FDA has announced its intention to separately require 510(k)s for these few devices, the Agency has failed to recognize that the scientific arbitrariness of these exemptions will lead to many additional high risk devices escaping oversight.

FDA intends to subject reprocessed single use devices to premarket submission requirements based on their original device classification as either Class I, II, or III devices, and not on their status as "high," "moderate" or "low" risk. Under this classification scheme, FDA and its expert panels have "exempted" certain new devices from 510(k) and PMA requirements because these requirements were not deemed necessary to ensure the safety of the devices. FDA intends to blindly extend these premarket exemptions to reprocessed devices even though the original expert panels never considered that these devices would be reused. The fallacy of automatically granting an exemption to a reprocessed single use device merely because an exemption was granted to the device for one use ignores the fact that reprocessing significantly changes the intended use of the single use device and that reprocessing adds substantial risks of infection or device failure that will adversely affect patient health and safety.

In the interest of patient safety and regulatory equity, FDA must require premarket submissions for ALL reprocessed single use devices, even where single use or reusable devices of the same type are exempt from these requirements.

Critical Data Elements Necessary to Show Safety and Effectiveness

In recent speeches. the FDA has indicated that it will clear or approve 510(k)s or PMAs for reprocessed single use devices despite a lack of data that demonstrates that the reprocessed devices can be safely and effectively reused multiple times. FDA intends to approve reprocessed devices on a demonstration that they can be reprocessed one time. This approval standard may protect the second patient, but not the third, fourth or twentieth. Such a policy would seriously jeopardize patient safety, and calls into question FDA's motivation for issuing draft guidance documents.

Devices are cleared or approved by FDA for either single use or multiple use. FDA's data requirements for multiple use devices are justifiably more rigorous than those for single use devices. Single use medical devices are designed with the intent for use on only one patient. Data in the 510(k)s of these devices support only this one use. Conversely, 510(k)s for multiple use devices must include data on the cleanability of the devices and their ability to withstand a pre-specified number of cleaning cycles without functional deterioration.

Reprocessors reprocess single use devices multiple times contrary to warnings from manufacturers and without adequate data on the effects of multiple sterilization processes on the functionality, material toxicity, sterilizability, and other appropriate parameters of the reprocessed devices. Reprocessors claim to validate their processes for multiple use, but as of yet, have not been required to obtain approval from FDA. FDA must not turn a blind eye to the reality of reprocessing and allow these devices on the market without data supporting a prespecified number of uses. If reprocessors cannot affirmatively demonstrate that their devices are safe and effective for multiple use, then those devices should not be used on U.S. patients. The FDA is not authorized to lower the standard for companies engaged in substandard practices.

The FDA must finalize its plan to require premarket submissions from reprocessors and must use the appropriate review standard for multiple use devices when reviewing premarket submissions from reprocessors. In an effort to make that review standard as transparent as possible, FDA should issue a guidance document

for FDA reviewers providing details of premarket application review for reprocessed single use devices. By making a review standard available to the public, FDA will ensure that patient safety is not sacrificed to inadequate data that does not support the safety and effectiveness of reprocessed single use medical devices.

Conclusion

In closing, I would like to thank the Committee for taking an active interest in this issue over the past year. Your continued oversight can only help to ensure that patients are protected by adequate regulation of single use device reprocessing.

Senator COLLINS. Dr. Clough, we are pleased to welcome you.

Dr. CLOUGH. Thank you, Madam Chairman. I am Dr. John Clough, a practicing rheumatologist and chairman of Health Affairs at the Cleveland Clinic Foundation in Cleveland, OH. I am here today on behalf of the AHA's nearly 5,000 members. We are pleased to have the opportunity to testify on the long-standing practice of reprocessing medical devices and the recent GAO report on this issue.

Many medical products can be safely reused. The AHA is unaware of any compelling evidence to demonstrate a problem with reprocessing many devices labeled as "for single use." In fact, the FDA on several occasions has indicated it does not believe reprocessing represents a risk to public health or safety. The GAO's report on medical device reprocessing confirms that the FDA believes reprocessing does not pose a risk to public health.

It states FDA has the authority to immediately halt any practice that threatens public health and has not done so with SUD reprocessing because it believes there is no evidence that the public health has been threatened. Historically, hospitals have been reprocessing medical devices for decades and they have expensive experience in device reprocessing. If this practice were a threat to patient safety, epidemiologists would long ago have identified resulting clusters of infection.

Only in the past 20 years has there been a marketplace explosion in the number of devices being labeled for single use. We understand manufacturers' desire to control which product they place on the market and the warranties they offer. However, the for-single use label is a misnomer. For example, in the last 2 years at the Cleveland Clinic, we have observed products such as orthopedic saw blades that had previously been shipped unsterile packaged in big boxes arriving now individually packaged with the "for single use" label with no observable change in the product other than the packaging.

The FDA should have the authority to regulate use of the label "for single use" and require manufacturers to justify placing this label on a device. Hospitals are already subject to significant regulatory and accreditation oversight by entities such as HCFA, the Joint Commission, and State licensing authorities. By contrast, only one outside source, the FDA, regulates manufacturers and third-party reprocessors. At the Cleveland Clinic, our cardiac electrophysiology laboratory reuses both nonlumen diagnostic electrophysiology catheters and nonlumen radiofrequency ablation catheters, an example of which is here. Both are currently labeled "for single use."

The price of each new ablation catheter is about $1,240. And we prorate charges down to $250 for subsequent uses. We pass these savings along to payers. Each procedure requires three to six cath-

eters and each catheter is used a maximum of five times. It is tested after each use for electrical and mechanical integrity and function and if it passes, it is then resterilized. Each year standard operating procedures are reviewed and patient outcomes are assessed.

Our lab has a series of continuous quality improvement projects to identify infections and other problems in patients undergoing procedures done in the lab. A recent review of the data on 3,230 electrophysiologic testing procedures and 1,708 radiofrequency ablation procedures showed no infections. 97 percent of these procedures used at least one reprocessed catheter.

The AHA has called upon the FDA to qualify its authority to regulate reprocessing performed at hospitals. In doing so, we do not suggest that hospitals be freed from appropriate oversight of their reprocessing activities, but the FDA's area of expertise is regulating device manufacturers, not hospitals. As we said earlier, many other agencies and organizations are charged with overseeing hospitals' activities. Treating hospitals as manufacturers does not make sense and would unnecessarily strain their already tenuous resources.

If hospitals are forced to comply with yet another layer of regulation, many facilities will abandon reprocessing. In the absence of evidence of any threat to patient safety, this action would merely add cost to the health-care system without improving patient outcomes. We believe the FDA should suspend its proposed guidance approach and proceed with a formal rulemaking process in accordance with the Administrative Procedures Act. A rulemaking process would afford the FDA the opportunity to design a regulatory structure that makes more sense for hospitals.

In conclusion, Madam Chairman, patient safety is the first and foremost concern of all hospitals and health systems. Appropriate reprocessing poses little or no risk to the public, as evidenced from the findings of the GAO report, the FDA, the CDC, infection control officials, risk managers and quality consultants. It represents responsible waste management and appropriate use of scarce health care resources. Thank you very much.

Senator COLLINS. Thank you, Dr. Clough.

[The prepared statement of Dr. Clough follows:]

PREPARED STATEMENT OF DR. JOHN CLOUGH

Mr. Chairman, I am John Clough, M.D., chair of health affairs at the Cleveland Clinic Foundation in Cleveland, Ohio. I am here today on behalf of the American Hospital Association's (AHA) nearly 5,000 member hospitals, health systems, networks, and other providers of care. We are pleased to have the opportunity to testify on the long-standing practice of reprocessing medical devices and the recent General Accounting Office (GAO) report on this issue.

The Cleveland Clinic Foundation, founded in 1921, integrates clinical and hospital care with research and education in a private, non-profit group practice. Last year at the Cleveland Clinic and Cleveland Clinic Florida, more than 850 physicians representing 100 medical specialties and subspecialties provided care for more than I million outpatients and close to 50,000 hospital patients.

I am a practicing rheumatologist with nearly 30 years of experience. As chairman of the Division of Health Affairs, I oversee government relations, community relations, fund-raising, and the volunteer program. I am involved in the institution's initiatives on protecting patient safety and preventing medical errors.

BACKGROUND

Reprocessing, resterilization and reuse were historically the norm in medical practice. For decades, hospitals have been engaged in resterilizing, repackaging and

reusing medical devices. Only in the past 20 years have disposable devices been introduced to the market.

The terms "reuse " and "reprocess" can encompass many scenarios, which can occur in multiple locations—hospitals, ambulatory surgical centers and physician offices. Some hospitals utilize the services of third-party reprocessors while others reprocess within their own facilities. In some cases, the medical device never touches a patient. For example, almost every day at the Cleveland Clinic we have a surgery cancelled or postponed, sometimes after the operating room has been prepped for the procedure. That preparation includes opening devices labeled "for single use," such as needles, scalpels, sponges and syringes. What becomes of these devices when the surgery is cancelled? Most of it would be unfortunately wasted as "medical trash," but because of increased environmental concerns and cost reduction initiatives, we have found that we can safely resterilize, inspect and repackage many devices for later use—a practice that does not pose a risk to our patients. The AHA commends the Food and Drug Administration (FDA) on its decision to exclude open-but-unused devices from the agency's proposed guidance on reprocessing devices labeled "for single use."

Another common scenario is the reuse of a non-critical device - one that does not penetrate a sterile tissue plane or mucus membrane during use, but may contact the patient's skin. For instance, a sequential compression device, which is used on the patient's leg to promote circulation and avoid deep vein thrombosis, is comprised largely of plastics and fits like a sleeve over a patient's leg. Hospitals routinely resterilize, inspect and repackage these types of devices.

Probably the most discussed reprocessing scenario is that of cleaning, sterilizing and repackaging a single-use, critical device after it has been used on a patient so it can be used again. Hospitals that reprocess critical devices do so using carefully designed protocols that ensure patient safety.

REPROCESSING MAKES SENSE

With constrained health care resources and a heightened commitment to the environment, reprocessing makes sense. I need only reiterate the slogans we now teach our children—that's the three R's—reduce, reuse, and recycle. AHA members are committed to being better stewards of the environment by pledging to reduce, not increase waste. In 1998, the AHA and the Environmental Protection Agency initiated a joint-partnership to reduce hospitals' total waste volume by 50 percent by 2010. Responsible waste management and recent cost reduction initiatives support the long-standing practice that hospitals can safely sterilize, inspect, and repackage many devices for later use.

NO EVIDENCE REUSE POSES A HEALTH THREAT

Many medical products can be safely reused as evidenced through decades of hospital experience in reprocessing both reusable devices and those labeled "for single use." The AHA is unaware of any evidence to demonstrate a problem with reprocessing devices labeled "for single use." In fact, the FDA on several occasions has indicated that it does not believe reprocessing presents a risk to public health or safety.

For instance, in an October 6, 1999 letter from David Feigal, MD, MPH, the Director of the Center for Devices and Radiological Health, to Larry Pilot, Esq. of McKenna & Cuneo, denying the Medical Device Manufacturer Association's Citizen's Petition to ban reprocessing, Dr. Feigal wrote, "In fact, FDA has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source." One year earlier, the FDA denied a similar citizen's petition from the Health Industry Manufacturer's Association, citing, among other things, a lack of evidence of adverse outcomes. At that time, the FDA specifically encouraged "trade and scientific organizations, OEMs [original equipment manufacturers], user facilities, and others to provide any data demonstrating adverse patient outcomes from the use of reprocessed 'single use only' devices," but noted that as of that time, the FDA had seen "no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes." (Letter to Nancy Singer, Esq., July 13, 1998.)

In his testimony before the Subcommittee on Oversight and Investigations, House Committee on Commerce on February 10, 2000, Dr. Feigal stated that in a review of the Medical Device Reporting reports received by Center for Devices and Radiological Health over the past three years, "we can discern no pattern of failures with reused SUDs [single use devices] that differs from patterns observed with the initial use of SUDs."

The GAO's June 2000 report on medical device reprocessing further confirms that the FDA believes reprocessing does not pose a risk to public health. It states, "FDA has the authority to immediately halt any practice that threatens the public's health and has not done so with SUD reprocessing because it believes there is no evidence that the public health has been threatened."

In its report, GAO also notes that "[h]ospital infection experts at the CDC [Centers for Disease Control and Prevention] told us that the evidence showed that SUD reprocessing posed minimal, if any, public health risk." CDC experts said that they were not aware of patient illness caused by SUD reuse in the last decade and that hospital infection surveillance systems they relied on would have uncovered those infections had they occurred. The GAO also stated that "several of the reports we identified of patient adverse events allegedly related to SUD reprocessing are inaccurate, not relevant to the debate or difficult to interpret."

Hospitals have been reprocessing medical devices for decades. If this practice threatened patient safety, epidemiologists would have identified long ago clusters of infection developing. However, as the FDA and the GAO confirm, there is no evidence to support the notion that reprocessing is a risk to public health.

The GAO study also confirms that the practice of reprocessing reduces costs. For example, hospitals that reprocess report annual savings ranging from $17,000 for pulse oximeter sensors (an externally applied device which measures blood oxygen levels) to $1 million for electrophysiology catheters. Reprocessing also reduces costs for all users, including facilities that do not reprocess. For example, GAO found that manufacturers sometimes offer lower prices on new devices to facilities that agree not to reprocess. In. one instance, a manufacturer agreed to match the price of a third-party reprocessor if the hospital agreed to buy new instead of reprocessing the device. GAO also had evidence that the overall prices of some devices labeled "for single use" that are commonly reprocessed appear to have decreased in recent years, some by as much as 20 percent.

RESTORE MEANING TO THE TERM "FOR SINGLE USE"

Original equipment manufacturers have little incentive to label devices as reusable and, in fact, have financial incentives to designate devices as "for single use." Manufacturers appear to use the term "for single use" as part of their labeling without justifying whether, in fact, the device can be safely reprocessed for subsequent use. We understand manufacturers' desire to control which products they place on the market and the warranties they offer. However, the "for single use" label is a misnomer. In the last two years at the Cleveland Clinic, we have observed products, such as saw blades, that have been labeled historically as reusable, arriving with the "for single use" label with no observable change in the product. We believe that the recent proliferation of costly devices labeled "for single use" that have replaced viable reusable products has contributed to the strain on health care resources.

The AHA believes the FDA should take steps to ensure that the label "for single use" is meaningful and not simply an attempt by manufacturers to increase sales. Currently, device manufacturers determine whether a device is labeled "for single use." However, the FDA should have the authority to regulate the use of the "for single use" label and require manufacturers to both justify labeling a device as "for single use" and provide scientific data specifying any resterilization or reprocessing techniques that might compromise the integrity of the device. We find it odd that the FDA intends to encroach upon an area in which it has no background, i.e., hospitals, but the agency declines to take the initiative to seek expansion of its authority over device manufacturers—an industry clearly in its jurisdiction.

As the owners of the data—much of it proprietary—on the functional specifications of their devices, manufacturers know the most about the ability of their devices to hold up to repeated cleanings and sterilizations. In an era of heightened attention to the environment and cost reduction measures, manufacturers should share that information with those of us who use medical devices and be actively involved in developing consensus standards regarding the reuse of such devices. Those devices that can be safely reprocessed and reused should no longer be permitted to carry the label "for single use."

OVERSIGHT OF REPROCESSING

Hospitals are subject to significant regulatory and accreditation oversight by entities such as the Health Care Financing Administration, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), state licensing authorities, and other county and city agencies, particularly with respect to patient safety and quality of care. By contrast, only one outside source—the FDA—regulates manufacturers and third-party reprocessors.

Hospital reprocessing activities are marked by a high degree of physician involvement, supervision and control. In many cases, a multi-disciplinary committee, such as the infection control committee, which typically consists of clinical staff (physicians and nurses) and operational staff (sterile processing, risk management, and materials management) oversees the reprocessing activities of health care facilities. This committee monitors reprocessing quality assurance and improvement activities, recommends strategies for improving performance, and reports such findings and

recommendations to the facility's performance improvement oversight committee, medical staff and governing body.

Through its membership, activities and reporting structure, this type of multi-disciplinary committee meets the requirements of numerous JCAHO standards, including those for surveillance, prevention and control of infection. Naturally, medical professionals and the health care facilities in which they practice have as their primary mission quality patient care. In pursuit of this mission, they have standards, policies and procedures for reprocessing in place.

At the Cleveland Clinic, for example, our cardiology electrophysiology laboratory reprocesses both non-lumen diagnostic electrophysiology catheters and non-lumen radiofrequency ablation catheters, both of which are currently labeled "for single use." Each catheter is used five times or less. It is tested after each use for electrical and mechanical safety and function, then resterilized. Each year, standard operating procedures are reviewed and patient outcomes are assessed. The sterilization practices are also regularly reviewed and staff competency assessed. Since 1993 our lab has had a continuous quality improvement project to identify any infections in patients who have had procedures done in the lab. Infection cases are then reviewed with the Infectious Disease Department.

Reprocessing standards, policies and procedures, in conjunction with the quality improvement program, are designed specifically to protect the well-being of hospital patients. Existing nonFDA regulatory oversight, which the AHA believes includes the components necessary to address and satisfy the FDA's concerns in this area, has resulted in the development of these processes. We are disappointed that the FDA ignored this existing oversight framework when crafting its proposed guidance.

For instance, JCAHO, during its announced and unannounced surveys, focuses heavily on patient safety. In addition to visiting patient care and reprocessing areas to observe infection control practices, JCAHO reviews the minutes of the infection control committee, the medical staff executive committee, the performance improvement oversight committee and the governing body. The inspectors look for evidence of sufficient reporting of performance improvement information and for action on performance improvement recommendations. Failure to adequately demonstrate compliance in these areas would result in substantial findings of noncompliance for the facility.

FDA'S STATUTORY AUTHORITY OVER HOSPITAL-BASED REPROCESSING

The AHA has called upon the FDA to articulate its rationale for claiming authority to regulate reprocessing performed at hospitals. We are not suggesting that hospitals not be subject to appropriate oversight of their reprocessing activities. The FDA's area of expertise is regulating manufacturers, not hospitals, and as we said earlier, numerous other agencies and organizations are charged with overseeing hospitals' activities.

However, even assuming the FDA has statutory authority over hospital reprocessing, we believe that the precedent-setting imposition of FDA manufacturing regulations on hospitals through a guidance document, rather than through a formal rulemaking process, is inconsistent with the requirements of the Administrative Procedures Act (APA).

The FDA's assertion of regulatory authority is apparently based on the premise that reprocessing is the legal equivalent of manufacturing. Under the current statutory and regulatory scheme, the FDA is charged with regulating the design, manufacture and commercial sale of medical devices. However, the AHA has not found an FDA statutory provision or any regulation that specifically addresses the issue of reprocessing a single-use medical device for subsequent reuse.

Reprocessing neither affects a device that is in the process of being delivered in an interstate commercial transaction nor results in a new product that is made available in interstate commerce. This calls into question the FDA's jurisdiction over reprocessing activities. In particular, for hospital-based reprocessing of devices, the device has already reached its final user, the physician, and is no longer in interstate commerce. When a product no longer remains in interstate commerce, the authority of the FDA to regulate ceases.

The FDA recognized as much when it established its policy with respect to reprocessing by health care facilities, as expressed in Compliance Policy Guide (CPG) 300.500, which, for over 20 years, has placed responsibility for hospitals' reprocessing and reuse of devices labeled "for single use" with the hospitals, without FDA oversight or affirmative regulatory requirements.

Treating hospitals as manufacturers doesn't make sense and could unnecessarily strain the resources of health care providers. For hospitals, reprocessing has had the historical benefit of allowing the treatment of a greater number of patients and the accrual of cost savings without sacrificing patient safety. At the Cleveland Clinic,

we prorate devices that are reprocessed, thereby passing along our savings to payers.

If hospitals are forced to comply with another layer of bureaucratic regulation, many facilities will abandon the practice of reprocessing, which will increase costs. Given that the FDA is unable to cite evidence of a threat to patient safety, such regulation will only add costs to the health care system but do nothing to improve patient outcomes. In fact, as the GAO report states "because the demonstrated health risks from SUD reprocessing are small, [the new FDA framework] may have only a limited impact on public health."

Even assuming that the FDA has statutory authority to regulate hospital reprocessing activities which we feel has yet to be proven—we believe that the FDA has not followed the requirements of the APA, which are necessary for the promulgation of legally binding regulations or rules. If the agency is issuing interpretative rules, general statements of policy or rules of agency organization, procedure, or practice, the procedures required by the APA do not apply.

In the case of the Enforcement Priorities guidance, the FDA is asserting that it has always had the authority to regulate reprocessing. Even assuming such jurisdiction, the Enforcement Priorities guidance is clearly much more than just interpretive rules or a general statement of policy. It is, in fact, an entirely new application of FDA regulations to hospital-based reprocessing. The Enforcement Priorities guidance imposes substantial and immediate burdens on hospitals, and violations could result in serious civil and criminal penalties and damage to reputations. This being the case, the guidance is regulation, and the FDA has not engaged in rulemaking in its promulgation.

Given this proposed precedent-setting expansion of the FDA's regulatory authority over hospital reprocessing activities, the agency—if it can prove that it has jurisdiction in this area—should suspend issuance of guidance and proceed with a formal rulemaking process in accordance with the APA. Such a rulemaking process affords the public, in this case our member hospitals, with all rights and remedies that apply when a regulation is promulgated. Further, because hospitals are not manufacturers and would have great difficulty complying with certain of the current provisions that apply to OEMs, a rulemaking process would afford the FDA the ability to design a regulatory structure that makes more sense for hospitals. It could also provide an opportunity to limit application of the regulation only to those devices whose characteristics make appropriate reprocessing more challenging.

In the event that such a rulemaking is undertaken, it is critical that any additional regulation include all health care facilities and other providers who engage in reprocessing activities, such as physician offices, group practices and ambulatory surgery centers. The GAO report supports this position: "By at least temporarily excluding ambulatory surgery centers, physicians' practices, and other nonhospital health care institutions from regulation, the proposal maintains the inconsistency of the current policy by exempting some categories of reprocessors from FDA oversight."

CONCLUSION

Mr. Chairman, patient safety is the first and foremost concern of all hospitals and health systems. Appropriate reprocessing poses little or no risk to the public, as evidenced from the findings of the GAO report, the FDA, the CDC, infection control officials, risk managers and quality consultants. It represents responsible waste management and appropriate use of scarce health care resources. In the absence of evidence that reprocessing and reuse of medical devices labeled as "single use," are a threat to patient safety, regulating reprocessing by treating hospitals as manufacturers adds costs without adding the benefits of increased patient safety or improved outcomes.

Senator COLLINS. Mr. Feltner.

Mr. FELTNER. Yes, good morning. The Association of Medical Device Reprocessors appreciates the opportunity to present testimony regarding the reprocessing of medical devices labeled as single use. My name is Vern Feltner and I am president of Alliance Medical, a member of AMDR.

AMDR is a trade association representing the legal and regulatory interests of third-party reprocessors of medical devices labeled "for single use." It is estimated that AMDR members perform approximately 80 percent of the third-party reprocessing done in the United States. AMDR supports a strong, rational, well-funded FDA regulatory regime as critical to ensuring the safety of reproc-

essed devices. FDA currently imposes a number of regulatory controls on third-party reprocessors and membership in AMDR requires compliance with all applicable FDA requirements.

And AMDR commends Senator Durbin for ensuring that FDA has sufficient funding for the regulation of medical device reprocessing. In AMDR's view, protecting patient safety must be the highest priority. And accordingly, FDA regulation of reprocessing should be based on demonstrated patient safety risk and not on hypothetical risk designed to provoke public alarm. Medical device reprocessing is safe.

However, the health care industry is not perfect and AMDR companies welcome the committee scrutiny of medical device reprocessing. We think that this process will lead to greater awareness of public awareness of reprocessing and ultimately to higher standards of safety. What we think is unfortunate, however, is that much of the opposition to reprocessing comes from original device manufacturers who review or who look at reprocessing as an economic threat and who stand to reap enormous financial gains by eliminating reprocessing as an option for hospitals.

Their strategy has been to attempt to portray reprocessing as unsafe. But facts are very stubborn things. The truth is that the safety record of reprocessing is excellent. As the GAO report found, proper reprocessing of certain devices labeled "for single use" is safe. This is the view of major hospital and physician groups and has been borne out in numerous peer reviewed scientific studies. AMDR companies themselves have reprocessed over nine million devices with scant few problems.

In order to ensure the safety of their devices, AMDR members adhere to several important safety principles including testing every single device before it is returned to the hospital requesting the reprocessing.

Another point that is crucial to this whole discussion is the single use label itself. Single-use labeling is at the sole discretion of the manufacturer even though they may well have data supporting multiple use of the device. And what we have seen is the single-use label being used for economic reasons, as a way to sell more devices, and not out of concern for patient safety. Hospitals that discard devices that could be safely reprocessed are wasting valuable resources that could be directed toward improvements in patient access and medical technology.

Proper reprocessing is a way for hospitals to maintain the highest quality patient care while also achieving significant cost savings. We believe that patient safety is of utmost concern, but health care cost containment is also of extreme importance. In this age of rising health care costs, proper medical device reprocessing is part of the solution.

Senator COLLINS. Thank you for your testimony.

[The prepared statement of Mr. Feltner follows:]

PREPARED STATEMENT OF VERN FELTNER

The Association of Medical Device Reprocessors (AMDR) appreciates the opportunity to present testimony regarding the reprocessing of medical devices labeled for single-use. My name is Vern Feltner, and I am President of Alliance Medical Corporation, a member company of AMDR. AMDR is a trade association representing the legal and regulatory interests of third-party reprocessors of medical devices la-

beled for single-use. It is estimated that AMDR members perform approximately 80 percent of the third-party reprocessing done in the United States. Members of AMDR serve a nationwide customer base of hospitals and outpatient surgery centers, and reprocess a limited set of devices in several clinical areas, including perioperative, cardiology, orthopedics, patient floor, and respiratory therapy. AMDR companies contract with hospitals in all 50 states and the District of Columbia, and reprocessing takes place in most of the elite hospitals of our nation. [1]

Reprocessing allows both rural and urban hospitals to provide all of their patients with quality health care in a climate of diminishing resources. Hospitals that take advantage of the benefits of reprocessing have more resources available to provide care to individuals who have traditionally lacked access to the health care system. As detailed in my testimony, hospitals and AMDR members view patient safety as their number one priority. Our excellent track record shows our commitment to safety. FDA has stated that it has "been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single-use device from any source. [2] The recently released U.S. General Accounting Office Report ("GAO Report") also confirms AMDR's longstanding view—that there is little available evidence of harm from reuse, but that FDA oversight is warranted. [3]

That is why, despite our strong safety record, AMDR is not here today seeking exemption from regulation and oversight. To the contrary, AMDR and the reprocessing industry seek a strong, rational regulatory scheme. When AMDR members first began reprocessing, we—on our own initiative - went to FDA and asked them to regulate us, and they have. Over the past year, FDA has been re-examining its policies with regard to reprocessing, and AMDR has been working closely with the agency. AMDR wants to emphasize that any regulatory scheme should be based on demonstrated public safety risks and not on hypothetical risks designed to provoke public alarm.

AMDR is pleased, though not surprised, that the GAO found that the proper reprocessing of certain devices labeled for single-use is safe. Concern for patient safety is why this Committee requested the GAO investigation, and we have consistently welcomed the examination. The GAO findings dispel some important concerns regarding infection. For example, hospital infection control practitioners informed GAO that " all types of infectious bacteria and some key viruses (including human immunodeficiency virus (HIV) and hepatitis C) can be destroyed if devices are properly cleaned and sterilized and that [the infection control practitioners] were not aware of any infections resulting from the reuse of [single-use devices] in their hospitals. [4] GAO also consulted with the head epidemiologist of the Centers for Disease Control and Prevention's (CDC) Hospital Infection Program, who said "that although CDC does not specifically monitor [single-use device] reuse, he was confident hospital infection surveillance systems would have uncovered infections resulting from [single-use device] reuse if they had occurred. [5] GAO also was told by an official of a health quality consulting organization that "his firm could find no evidence in its databases that treating patients with reprocessed [single-use devices] was more dangerous than using new devices. [6]

The GAO Report also confirms the significant savings that hospitals can achieve through reprocessing. Third-party reprocessors offer hospitals on average a 50% savings as compared to purchasing a new device. Further savings result from the market competition presented by reprocessing, which has forced original equipment manufacturers (OEMs) to lower the prices of new devices. Finally, GAO found that "many health care professionals . . . believe manufacturers market devices with a "single-use" label because of the economic benefits of doing so and that they therefore believe many [" single-use" devices] can be reused. [7] Though reprocessing is a small part of the $56 billion medical device industry, reprocessing poses an economic threat to OEMs; thus, there exists a strong incentive to label devices as "single-use" when, in fact, such devices may be appropriate for reuse. As further discussed in this testimony and confirmed by the GAO Report, proper reprocessing of certain de-

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[1] For a list of the top U.S. hospitals, see "America's Best Hospitals," U.S. News & World Report, July 19, 1999, at 61.

[2] Letter from David W. Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry P. Pilot, McKenna & Cuneo. See Attachment A.

[3] U.S. General Accounting Office Report entitled "Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted," June 2000.

[4] GAO Report at 14.

[5] Id.

[6] Id.

[7] GAO Report at 7-8.

vices labeled as single-use poses no threat to public health and enables hospitals to conserve limited health care resources.

I. HISTORY AND BACKGROUND

Over Two Decades of Successful Reprocessing. From the recent interest in our industry, one might believe that reprocessing of medical devices labeled for single-use is new, uncharted territory. One might also assume that reprocessing is a haphazard practice applied indiscriminately to all medical devices. In fact, both of these assumptions are entirely false. The reprocessing of certain medical devices labeled for single-use has taken place for over two decades. The American Hospital Association (AHA) calls reprocessing of "single-use" devices "a safe and standard medical practice" that hospitals have used "for years with excellent success." The American College of Cardiology wrote to Congress that "there are cardiovascular specialists who have been using reprocessed catheters in their labs for more than 20 years and cannot cite a single instance where a reprocessed catheter has broke[n] or caused infection." And the Mayo Clinic states that "for more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection. [8]

Hospitals originally began to reprocess devices labeled for single-use approximately two decades ago, when OEMS began to change the label on certain products from reusable" to " single-use," without making any structural modifications in the device. Doctors and nurses recognized the inherent waste in discarding these devices after one use. Practitioners were also aware that the single-use designation is not based on a determination by FDA. To the contrary, the single-use label is chosen by the OEMs, and for the devices we reprocess, the single-use designation is a marketing decision, not a safety decision. The reality is that OEMs have little incentive to cut into their own profits by endorsing the reprocessing of certain devices. The math is easy - the more devices that are reprocessed, the fewer brand-new devices are purchased, and that much less money is made by manufacturers.

Making the Decision to Reprocess. Hospitals do not reach the decision to reprocess lightly. Rather, they rely on committees made up of physicians, nurses, sterile processing professionals, infection control specialists, risk managers, and hospital lawyers to determine whether a specific device can and should be reprocessed. AMDR companies carefully scrutinize every device to determine whether it can be safely and effectively reprocessed. As a result of this rigorous selection process, only a small percentage of the thousands of medical devices used by hospitals are actually being reprocessed by our companies. [9] Indeed, it should be noted that several of the devices on the " List of Frequently Reprocessed Devices" contained in the GAO Report are not reprocessed by AMDR companies. [10]

Categories of Devices Labeled for Single-use That are Reprocessed. AMDR members reprocess three categories of medical devices labeled for single-use: 1) opened devices that have never been used; 2) unopened devices whose expiration date has passed; and 3) previously utilized devices. All three of these categories are reprocessed in compliance with the rigorous quality assurance requirements contained in FDA's Quality System Regulation.

II. THIRD-PARTY REPROCESSING IS AN FDA-REGULATED INDUSTRY

In the past, manufacturers have claimed that third-party reprocessing is an "unregulated" industry. The fact is that FDA has regulated third-party reprocessors ever since our member companies came into existence—we even invited FDA's regulation! Third-party reprocessors are currently required to comply with a number of FDA regulatory requirements, the most significant of which is the Quality System Regulation. The Quality System Regulation is an extensive set of quality assurance provisions governing every aspect of a reprocessor's operations, including production and process controls, process validation, control of non-conforming product, and finished device acceptance. Pursuant to these Quality System Regulation requirements, reprocessors must document that they have developed comprehensive systems to assure that a reprocessed device is clean, sterile, and able to perform its originally intended clinical function. See 21 C.F.R. Part 820. The functional testing step of reprocessing differs significantly from the testing performed by device manufacturers: AMDR companies functionally test every single reprocessed device before sending it back to a hospital, whereas device manufacturers test only a small sampling of their finished devices. We hear from many hospitals that they prefer to use

[8] See Attachment B for these and other letters from physician and hospital groups.

[9] See Attachment C for a list of the sixteen families of devices (including open and unused) that AMDR companies reprocess.

[10] For example, AMDR members do not reprocess any of the products listed as Respiratory Devices" nor do they reprocess hemodialysis blood tubing, sharp containers, "syringes, piston," or "infusion pumps, implanted." See GAO Report at Appendix 1.

devices that we have reprocessed, precisely because they know that each device has been individually tested for functionality.

Third-party reprocessors must make all required Quality System Regulation information and data available for FDA inspection, and firms that fail to comply with these requirements are subject to agency enforcement action. In addition to complying with Quality System Regulation requirements, third-party reprocessors also are required to: (1) register with the agency; (2) comply with FDA labeling controls; (3) and adhere to Medical Device Reporting (MDR) regulation requirements. Pursuant to MDR requirements, third-party reprocessors must report to FDA certain device malfunctions and device-related patient adverse events.

III. WHEN DONE PROPERLY, THIRD-PARTY REPROCESSING IS SAFE

The bottom line for today's hearing is whether the reprocessing of devices labeled for single-use is a safe practice. AMDR's expectation is that after hearing and reading our testimony and the GAO Report, and examining the available scientific data and the safety record of reprocessed devices, the HELP Committee will conclude with great certainty that this practice is not only safe, but economically and environmentally beneficial.

1. The Safety Record Of Reprocessed Devices Is Excellent

The facts are as follows: AMDR member companies have collectively reprocessed over 9 million devices labeled for single-use with very few problems. Indeed, FDA itself recently stated that it "has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single-use device from any source."[11] Similarly, a physician with the Centers for Disease Control and Prevention remarked that he "would just be absolutely amazed if [reprocessing] is a major health problem and the [leading hospitals] have failed to realize it."[12] Finally, the GAO reported that infection control and patient safety experts stated " that the reprocessing of certain ["single-use" devices] is not a demonstrated public health risk . . .".[13] The GAO Report goes on to note that "[s]everal reports of adverse events allegedly related to ["single-use" device] reprocessing that [GAO] investigated were inaccurate, not relevant to the debate, or difficult to interpret."[14] The GAO Report cites alleged problems with reprocessed devices, which have been highly publicized by the OEMs—but which have proven to be irrelevant to this discussion; this demonstrates the OEMs' propensity to confuse the public with alarming anecdotes that are unrelated to the safety of the devices AMDR companies reprocess.[15]

Pursuant to FDA's MDR regulation, hospitals must notify FDA when they learn that a device may have caused or contributed to a patient death or serious injury. 21 C.F.R. Sec. 803.30. Such events are reported to FDA on the MedWatch Mandatory reporting form. Significantly, the Mandatory MedWatch reporting form requires "user-facilities" (hospitals, nursing homes, etc.), manufacturers, and distributors to provide information regarding whether the device in question was labeled as single-use, and whether the adverse event involved the initial use or reuse of the device.[16] AMDR supports efforts by Senator Durbin to require that this information also be provided on the MedWatch Voluntary reporting form, which is used by health professionals within a "user-facility" who wish to report device-related adverse events." Indeed, as noted in the GAO Report, the MDR System for tracking adverse events for all devices (including new devices) is less effective than it could be. AMDR agrees with the GAO's findings and intends to work with FDA as needed to improve reporting.[17]

Every year, FDA receives over 100,000 MDR reports. Significantly, there has been only a handful of MDR reports associated with reprocessed devices. Indeed, FDA itself remarked that the number of MDR reports involving reprocessed devices is "tiny" compared with other problems.[18] Furthermore, the incidents reported in the few MDRs involving reprocessed devices are identical to problems that have occurred in new devices. Thus, it is not at all clear that these incidents were caused by reprocessing.[19]

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[11] Letter from David W. Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, McKenna & Cuneo. See Attachment A.

[12] Lauran Neergaard, Debate on Reuse of Medical Devices, Associated Press, August 13, 1999.

[13] GAO Report at 12. (Also see p. 14)

[14] GAO Report at 12.

[15] See GAO Report at 16.

[16] See MedWatch Mandatory reporting form, Sections H5 and H8 (Attachment D).

[17] GAO Report at p. 18.

[18] Device & Diagnostics Letter, Vol. 26, No. 48 (Dec. 17, 1999) at 1.

[19] As one example, an MDR report was submitted to FDA concerning a reprocessed electrophysiology (EP) catheter whose tip became detached. MDR Report Number 1062310-1999-00001. See Attachment E. However, the identical incident has been reported for new EP cath-

There are Thousands of MDR Reports on Brand New Devices Each Year. The OEMs have made much noise about the handful of MDRs associated with reprocessed devices. Attached to my testimony is a chart of some of the MDRs for the OEM companies leading the attack on reprocessing, demonstrating that there are thousands of examples of medical devices causing patient injury (and occasionally death) during their first use.[20] A specific example was a 1994 outbreak of post-surgical infections that has been attributed to bacteria-contaminated sutures manufactured by Ethicon, Inc. (Ethicon), a division of Johnson & Johnson. The contamination allegedly resulted from a malfunction in Ethicon's sterilization system.[21] Ethicon ultimately recalled 3.6 million packages of sutures.[22] As another example, FDA recently found that an improperly functioning coronary stent system manufactured by Boston Scientific Corporation had caused 26 patient injuries, and may have been a factor in the death of one individual.[23] We cite these examples to show that the use of medical devices is not, and will likely never be, 100 percent risk-free. That said, the reprocessing industry believes that having one injury is still one injury too many, and we will continue to strive to make our services as safe as possible.

2. The Receipt Of Warning Letters Does Not Necessarily Mean That The End Product Is Unsafe

The device manufacturers also cite FDA Warning Letters received by certain third-party reprocessors; as evidence that third-party reprocessing is unsafe. Once again, the manufacturers are not applying their own logic to themselves. While it is true that some third-party reprocessors have been issued FDA Warning Letters, many OEMs have also received FDA Warning Letters. Indeed, FDA often issues Warning Letters to device manufacturers.[24]

By way of background, a Warning Letter is based upon an FDA inspector's observations and is not independently verifiable by a court or other impartial finder of fact. A Warning Letter is informal and advisory, and constitutes only an FDA communication that the agency considers a violation to exist.[25] Typically, the company in question addresses the concerns raised in the Warning Letter, and FDA re-inspects the facility to ensure that any necessary changes have been made.[26]

By failing to frame FDA Warning Letters in their proper perspective, and by choosing not to disclose that manufacturers themselves often receive Warning Letters, the manufacturers clearly hope to create the impression that FDA has singled out third-party reprocessors for some sort of special scrutiny. This is not the case. Actually, a discussion of our receipt of Warning Letters helps prove our case—that reprocessors; are subject to FDA oversight, and that oversight is active. While AMDR members have full confidence in the safety and efficacy of their operations, we recognize that there is always room for improvement, and we welcome FDA's input in this regard. But, if the receipt of Warning Letters means that reprocessed devices are inherently unsafe, then brand new devices also should be considered inherently unsafe. We do not believe this line of thinking is logical and urge the manufacturers to be consistent in their application of the facts.

3. A Substantial Body Of Peer-Reviewed Scientific Literature Demonstrates The Safety Of Reprocessing

Physician and hospital groups have articulated strong support for reprocessing. There is also a significant body of independent, peer-reviewed scientific literature confirming the medical community's confidence in the safety of reprocessing devices labeled as single-use. Indeed, studies demonstrating the safety and efficacy of reprocessing have been published in a number of highly esteemed medical journals,

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eters. MDR Report Numbers 4501350000-1995-0088 and 6000087-1998-00002. See Attachment F.

[20] See Attachment G.

[21] See, e.g., Lance Williams, "Common thread in illnesses: sutures lawsuits blame postsurgical infections on a single source," San Francisco Examiner (Feb. 21, 1999); Lance Williams, "Patients wounded by infections across the country, lives have been torn by post-op complications," San Francisco Examiner (Feb. 21, 1999); Lance Williams, "How suture maker kept lid on infection suits despite recall, Ethicon said product was harmless," San Francisco Examiner (Feb. 22, 1999); Lance Williams, "Patients who suffered," San Francisco Examiner (Feb. 22, 1999).

[22] See, e.g., FDA Enforcement Reports 94-43 & 95-08.

[23] See, a.g., Ronald Rosenberg, "Boston Scientific, FDA spar over stent," The Boston Globe (October 10, 1998).

[24] FDA's Center for Devices and Radiological Health issued 303 Warning Letters in 1999. See www.fda.gov/foi/warning.htm and Thompson.com, an FDA Warning Letter Monitor.

[25] See Regulatory Procedures Manual at Ch. 4; FDA Office of Regulatory Affairs Warning Letter Reference Guide (October 4, 1994) at p. 14.

[26] As an example, we are including an FDA letter issued to an AMDR member company indicating that, in FDA's view, the concerns raised in the Agency's Warning Letter had been adequately addressed. See Attachment H.

including *Gastrointestinal Endoscopy, The American Journal of Gastroenterology, Journal of the American College of Cardiology, Journal of Thoracic Cardiovascular Surgery, Pacing and Clinical Electrophysiology (PACE), American Journal of Cardiology, Medical Journal of Australia, Canadian Journal of Surgery, and Canadian Journal of Cardiology.* [27]

What is most striking about the rigorous body of scientific evidence supporting the safety and efficacy of reprocessed devices is its dramatically superior quality, as compared to the "studies" offered by the 0EIVIs that oppose reprocessing. Indeed, most of the "scientific evidence" submitted by the opponents of reprocessing should be disregarded, as: (i) much of it was conducted by the OEMs themselves, rather than independent entities, and, as such, is tainted by the OEMs' clear economic incentive to portray reprocessing in a negative light; and (ii) much of it is plagued by fundamental scientific deficiencies, such as lack of an adequate sample size, and, as a result, cannot serve as a basis for any conclusions about the safety of reprocessed devices.

4. Tracking And Tracing Systems For Reprocessed Devices Help Ensure Accountability And Safety

AMDR companies take several steps to ensure appropriate tracking and tracing of the devices they reprocess. For example, AMDR companies do not commingle devices among hospitals. Rather, once our companies make a determination that a specific type of device can be reprocessed, AMDR members reprocess the device and return the same device to the hospital who requested the reprocessing—the hospital retains ownership of the device throughout the process. In addition, AMDR members employ numerous mechanisms, such as sophisticated bar code tracking systems, to monitor the reprocessing history of the device. Likewise, some reprocessors provide hospitals with "peel-off" labels, which can be placed in a patient's record to enable the hospital to determine whether a reprocessed device was used and where the device was reprocessed.

5. Proper Reprocessing Does Not Require Access To The Manufacturer's Specifications

One the most misleading arguments made by the manufacturers is that third-party reprocessors are incapable of safely reprocessing devices labeled for single-use because they lack access to the original manufacturer's specifications. Access to manufacturers' specifications is unnecessary because third-party reprocessors employ a variety of techniques to equip themselves with intimate knowledge about the workings of every device they reprocess. For example, in addition to utilizing every publicly available source of product-related information, o.g., product labeling and marketing materials, AMDR members also use independent laboratories to "reverse engineer" certain devices. AMDR member companies also are engaged in an ongoing dialogue with the clinical users themselves, i.e., the hospitals and physicians, in order to understand the performance requirements for each device they reprocess.

More importantly, pursuant to FDA's Quality System Regulation requirements, AMDR member companies have developed validated protocols to ensure that every device they reprocess is clean, sterile, and functional. If an AMDR member lacks sufficient information about a device in order to safely reprocess it, then that device will not be reprocessed. Furthermore, as described above, AMDR members—unlike manufacturers—perform functionality testing on ever single device that they reprocess. Thus, the manufacturers' argument that access to the original specifications is necessary to safely reprocess devices labeled for single-use is without merit. Indeed, if the manufacturers were correct in this claim—and they are not—it certainly is difficult to understand why so many hospital and doctor groups have endorsed the use of reprocessed devices.

IV. THE MANUFACTURERS' ALLEGATIONS ARE BASED ON ONE OVERRIDING CONCERN: ECONOMICS

Manufacturers Want to Erect Economic and Regulatory Barriers to Market Competition. There is little, if any, factual basis for the vast majority of objections to third-party reprocessing. The OEMs have chosen to disregard the significant body of scientific data supporting the safety of reprocessing, and instead have embarked on a crusade at the federal and state level to eliminate third-party reprocessing. This is not a surprise. Hospitals are fully aware that the "single-use" label on a medical device does not necessarily mean that it must be discarded after one use. As the AHA noted, "[i]n our view, the real issue is not whether reuse is appropriate, but whether the single-use label is a complete and accurate representation of the device." [28] For hospitals, proper reprocessing offers a way to maintain the highest quality patient care, while also achieving significant cost savings.

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[27] See Attachment I for a bibliography and summary of these studies.
[28] See Attachment B.

A. The Manufacturers, Call for "Informed Consent" Is Simply A Prong of Their Economic Argument

As part of their campaign to create an "aura" of suspicion around third-party reprocessing, the manufacturers argue that the very doctors committed to treating and curing the sick are keeping patients "in the dark" about the alleged hazards of third-party reprocessing. Indeed, the manufacturers advocate vociferously for mandatory "informed consent" regarding the use of reprocessed devices.

Although dressed up in the garb of patient safety, the manufacturers' informed consent argument is merely another prong of their economic agenda. Medical ethicists state that the objective of informed consent is to arm patients with sufficient information to make a prudent judgment about their medical care. If a physician believes that the use of a certain device or procedure will increase a patient's risk, then the physician should disclose this to the patient. Properly done, third-party reprocessing presents no additional risk to patients. Because properly reprocessed devices are as safe and effective as new devices, there is no ethical basis for requiring informed consent before the use of reprocessed devices.

Should There be Informed Consent for New Devices? It is striking that, although they push vigorously for informed consent with respect to the reprocessing of devices labeled for single-use, the manufacturers conspicuously avoid the obvious implications of their own argument. According to the manufacturers, a physician should be required to obtain the consent of a patient before using any device that has been reprocessed, because the reprocessed device allegedly poses an elevated risk. Of course, an elevated risk has not been established. According to this line of reasoning, surely it would be appropriate to require informed consent for use of new devices that have been the subject of an MDR report, Warning Letter, or recall. Similarly, it seems only logical that the manufacturers would demand informed consent with respect to the "second use" of devices that are labeled reusable. The manufacturers do not make these arguments because they realize that informed consent regarding MDR reports, Warning Letters, and recalls would be detrimental to their own economic interests.

Clearly, any possible rationale for requiring informed consent for reprocessed medical devices evaporates once FDA's draft guidance documents are finalized. As already discussed, the current regulatory scheme has ensured a very high level of safety for reprocessed devices that precludes the need for patient informed consent. Thus, under FDA's new scheme—which will impose the same premarket review requirements on reprocessors that OEMs face—any argument for informed consent is completely obviated.

B. Manufacturers Frequently Designate a Device As "Single-Use" For Economic Reasons, Rather Than Out Of Concern For Patient Safety

FDA does not require manufacturers to designate any devices as "single-use" only. There are no FDA regulations or formal standards distinguishing the quality or functionality of reusable devices from single-use devices. The discretion to label a device as single-use lies solely with the device manufacturer. As the GAO Report noted: "In effect, because FDA can only evaluate a device relative to the use intended for it by its manufacturer, its approval of a device as single-use means that a device can be used safely and reliably once, not necessarily that it cannot be used safely and reliably more than once if it is appropriately reprocessed."[29]

The "Single-Use" Label Provides Little Indication of the Product's Useful Life. The device manufacturers have repeatedly contended that devices labeled for single-use must be discarded after one use because they are manufactured in such a way that makes reuse prohibitive. In fact, it is nearly impossible to manufacture a medical device for "one use, and only one use." For example, a surgical instrument labeled for single-use does not "wear out" simply because it was used in a surgical case that took three hours rather than two hours. Likewise, it is absurd to suggest that if a scissors labeled for single-use is used to snip only once in a surgical case, then its entire useful life has been exhausted. In reality, a manufacturer's "single-use" designation on a medical device provides little indication of the product's useful life. The key issue should be the device's functionality. If a device labeled for single-use can be properly cleaned, packaged, and sterilized without negatively affecting its functionality, it can, and should, be used again.

Evidence that manufacturers often designate devices as single-use for economic reasons, rather than out of a concern for patient safety, is abundant and, as GAO found, contributes "to the sense that compliance with the single-use label is not always necessary."[30] For example, the December 11, 1998, episode of NBC's "Dateline" exposed Johnson & Johnson's practice of labeling as "single-use" contact

[29] GAO Report at 4 (emphasis added).
[30] GAO Report at 11.

lenses [31] that were virtually identical to the lenses that the company had been marketing as reusable. Thus, consumers were needlessly discarding lenses after one use. When asked why it had designated the lenses as single-use, Johnson & Johnson stated: "If we had changed the label and marketed for general use, then we couldn't advertise and create this single-use, daily disposable category. We made that decision because we felt it was a good business decision to do it that way. [32]
added).

Another example is a letter written by USCI Cardiology & Radiology Products (USCI) to a hospital explaining that, although USCI had decided to change the label on a particular device from reusable to single-use, it had made no structural changes to the device. Specifically, USCI stated: "[O]ur manufacturing processes of Woven Dacron Intracardiac Electrodes have not changed. These electrodes are made with the same materials and in the same manner they have been in the past." [33] In another example, Microvasive, a division of Boston Scientific Corporation, advised hospitals that, although Microvasive's hemostatic probes are labeled for single-use only, they may be reused under certain circumstances. Specifically, the Microvasive notice states: "BICAPO Hemostatic Probes are recommended for single-use only. However, this recommendation does not prohibit reuse under certain specific conditions. . . ." [34]

In light of the above evidence, the manufacturers' protestations that the single-use designation on a device is never arbitrary, and that "economics must be subordinate to this concern for proper health" [35] ring hollow. The reality is that, while many devices that carry a single-use label are not suitable for reprocessing, some are. Every product whether it is labeled "single-use" or "reusable" - must be assessed individually to determine whether it can be cleaned, packaged, and sterilized without impairing its functionality. Hospitals, and their doctors and nurses, should not be forced to needlessly discard devices labeled for single-use that could be safely reprocessed. Hospitals should be free to redirect their limited resources where they are truly needed—toward improvements in patient access and medical care.

C. Reprocessed Devices are More Affordable, and Market Competition Exerts Downward Pressure on the Price of New Devices

Third-party reprocessing represents a potentially formidable economic threat to manufacturers. A future where hospitals no longer needlessly discard certain devices labeled for single-use could, ultimately, mean a future of lower profits for manufacturers. The fact is that reprocessing has already had a substantial impact on the sales and profits of device manufacturers. Indeed, every time a hospital chooses to reprocess a device rather than purchase a new device, that means a lost sale for manufacturers. In addition, in an effort to persuade their customers not to reprocess, manufacturers have lowered the price of their devices. Lower prices generally mean lower profits.

The experience of one hospital that utilizes third-party reprocessing services is particularly telling. EP Technologies, Inc., a division of Boston Scientific Corporation, informed the hospital that it would be willing to supply [the hospital] with new catheters at the price of each returned catheter, if I (the hospital's Chief of Infection Control Service) would stop reprocessing . . . Being dumbfounded with this offer for cutting the price in half for each new catheter, I immediately asked her (the E.P. Technologies representative) where her integrity was with keeping the price so high all this time? She had no answers. [36]

The GAO Report found similar instances of OEMs lowering their prices in response to the competition presented by reprocessing. For example, the GAO was told by two hospitals that " manufacturers offered to reduce the price of new EP catheters by as much as one-half, matching the price of third-party reprocessing, if the facilities would agree not to reprocess." [37]

Not surprisingly, the device manufacturers fail to acknowledge that their opposition to third-party reprocessing is rooted in economics. Rather, they repeatedly assert that their primary motivation is patient safety. While emotionally appealing, the manufacturers' professed interest in patient safety is disingenuous at best. As

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[31] AMDR members do not reprocess contact lenses.
[32] Transcript of December 11, 1998, Dateline episode at 5 (emphasis
[33] See Attachment J.
[34] See Attachment K.
[35] Josephine Torrente, President, Association of Disposable Device Manufacturers, testimony to Illinois State Board of Health Board Meeting and Public Hearing Regarding the Reprocessing of Medical Devices Labeled for Single-Use, December 10, 1998.
[36] Letter from Dana Gruber, Chief, Infection Control Service, Brooke Army Medical Center, to William B. Stoermer, Jr., Executive Vice President, Alliance Medical Corporation (December 29, 1999). See Attachment L.
[37] GAO Report at 19.

set out in this testimony, third-party reprocessing is a safe, federally-regulated industry. When performed properly, third-party reprocessing poses no threat to patient safety.

V. FDA'S DRAFT GUIDANCE DOCUMENTS

As already stated in this testimony, AMDR supports strong, rational FDA regulation of reprocessing of medical devices labeled for single-use. In AMDR's view, patient safety must always be the highest priority, and vigorous FDA oversight of reprocessing is critical to ensuring the safety of reprocessed devices. AMDR believes that the rigorous regulatory framework currently enforced by FDA is well-suited to protecting patient safety. As detailed above, under FDA's current regulatory regime, third-party reprocessors are required to comply with a number of regulatory requirements—registration, listing, labeling, MDR, medical device corrections and removals requirements, and, most importantly, Quality System Regulation requirements.

The safety record of third-party reprocessing under the current, Quality System Regulation-centered regime has been excellent, and there is no evidence to suggest that changes in the regime are necessary to protect public health. However, because of pressure from OEMs who wish to eliminate the economic competition presented by reprocessing, FDA has decided to impose premarket review requirements on medical device reprocessors. While AMDR does not believe that premarket review is necessary to protect patient safety, AMDR members are prepared to comply with such a requirement. As FDA moves forward to finalize its premarket review scheme, AMDR is working with the agency to assure that the new requirements are implemented in a reasonable, risk-based manner, taking into account the strong evidence of the safety of medical device reprocessing, as well as the potentially serious consequences of unnecessarily restricting reprocessing. Indeed, if the regulatory burden imposed on reprocessing becomes so onerous that reprocessing is eliminated as an option for hospitals, certain medical devices and procedures will no longer be available for some patients because they will simply be too expensive. Thus, over-regulation of reprocessing would have a direct and negative impact on patients.

VI. CONCLUSION

As we have demonstrated, when performed properly, third-party reprocessing is safe. Third-party reprocessors are required to comply with a host of FDA requirements. Hospitals that take advantage of the benefits of third-party reprocessing can maintain the highest quality patient care, while also achieving significant cost savings. Resources saved through third-party reprocessing can be redirected toward improvements in patient access and medical technology. We believe patient safety is of utmost concern, but health care cost containment is also of extreme importance. In this age of rising health care costs, reprocessing is one of the few technologies that offers a solution.

Senator COLLINS. Ms. Cofiell, would you please proceed?

Ms. COFIELL. Thank you, Senator Collins. It is a pleasure and a privilege to present the viewpoint of our association to you this morning in the matter of reuse of single-use medical devices. The International Association of Healthcare Central Service Material Management, IAHCSMM, with membership of approximately 8,500 professions, is the largest organization in the Nation representing sterile processing technicians, supervisors and directors. The IAHCSMM's only agenda in connection with the issue of reuse is the safety of the patient and the delivery of quality care to the patients requiring surgery in our health care facilities.

Why does IAHCSMM consider the reprocessing of single-use devices in health care facilities to be a serious patient safety issue and why do they continue to support FDA regulation of healthcare facilities and third-party reprocessors that engage in reprocessing single-use devices? There are many reasons, but first and foremost and what I will address today is the lack of understanding on the part of many of how complicated reprocessing a single-use device really is.

The second sentence of the GAO report gives us these words: Reprocessing involves cleaning and sterilizing a device and verifying that it functions properly. Sounds simple as one, two, three, and it

is done. We would love it if that is the way it really was and if it were, we would not have the situation we have right now.

So I am going to use these few minutes to try and convince you how serious this reuse situation is and why IAHCSMM takes the position it does. If you have read our written statement, you know we keyed in on some of the intricacies involved in just the first step, cleaning, if it is performed correctly. And I am quoting a recommended practice from ECRI, "use pyrogen-free water for cleaning and rinsing, specify washing method, what detergent, what dilution, what water temperature, the duration of each step, what tools are necessary for disassembly and cleaning, and if it is an automated system, it should be fully defined, time, temperature, and solutions. Material compatibility determines what agents can be used."

There are over 6000 hospitals in the United States. If only 20 percent of them, and we know the number is much higher, are reprocessing single-use devices, that is 1,200 hospitals out there doing their thing. Are they using their recommended practices for reusable items? If so, that is not good enough. The materials used in single-use devices are usually different. They need to be tested. Can you steam sterilize at 270 degrees or will that affect the material? Does it need low temperature sterilization? If so, is ethylene oxide the choice or do we use another alternative? Do we have to do residual testing? This is the real world of reprocessing.

Central service departments do a great job of reprocessing reusable devices, thousands of them daily, because they follow recommended practices such as those provided by the Association for the Advancement of Medical Instrumentation, AAMI, and they can get reprocessing instructions from the device manufacturers. That is a regulation now since 1996. But for single-use devices, the hospital is on their own and they need regulation. Someone has to question what they are doing and how they are doing it.

Regulations should bring about a quality system that is needed to ensure a quality product. So we do not know if the implementation of the regulation will go smoothly. No doubt it is going to be difficult but IAHCSMM is committed to the outreach and education that will be required and we will help in any way we can. We feel the time is now. It is the right thing to do and IAHCSMM is looking forward to it happening.

Senator COLLINS. Thank you very much for your testimony.

[The prepared statement of Ms. Cofiell follows:]

PREPARED STATEMENT OF ANNE COFIELL ON BEHALF OF THE INTERNATIONAL ASSOCIATION OF HEALTHCARE CENTRAL SERVICE MATERIALMANAGEMENT (IAHCSMM)

The International Association of Healthcare Central Service Materiel Management (IAHCSMM) is a non-profit association with a membership of approximately 8,500 healthcare central service/materiel management professionals, actively performing the functions of sterile processing and materiel management across the nation and around the world.

The IAHCSMM mission is to provide healthcare facilities and the members of the Association with organized educational opportunities, professional development, a forum for information exchange, member services in response to member identified needs and priorities; and to represent Central Service Materiel Management in the professional community.

The IAHCSMM's only agenda in the issue of reuse of single-use devices (SUD's) is the safety of the patient and the delivery of quality patient care. We come to the table with no outside influences or funding. The IAHCSMM has nothing to gain or

lose from the final outcome of the decisions that will be made regarding the reuse of SUD's.

In the Spring of 1999, the IAHCSMM was invited to co-sponsor an AAMI/FDA Conference on Reuse of Single-Use Devices. At that conference, held on May 5-6, 1999, a Position Statement was presented by the IAHCSMM. The statement was formulated with input from our membership and received a unanimous vote of approval from our Board of Directors.

The IAHCSMM Position Statement on the Reuse of Single-Use Devices follows:

"The reuse of single-use medical devices is a very controversial, complex issue. IAHCSMM's position is that we must always promote quality healthcare and assure patient safety with positive outcomes. These issues must not be overlooked when evaluating the legal, ethical, financial and technical aspects of reprocessing medical devices labeled for single use, or considering a third party reprocessing company.

The Food and Drug Administration (FDA) has made it very clear in its Compliance Policy Guide No. 7124.23 that "the institution or practitioner who reuses a disposable medical device should be able to demonstrate: (1) that the device can be adequately cleaned and sterilized, (2) that the physical characteristics or quality of the device will not be adversely affected, and (3) that the device remains safe and effective for its intended use."

Reprocessing a disposable medical device requires a vast amount of testing, validation, and documentation. In today's healthcare setting, there are very few Central Service departments equipped to adequately deal with these requirements. The validated cleaning, sterilization and testing, for example, require specialized equipment functions which are not commonly available on equipment in general use. Often the manufacturers' recommendations for reprocessing that are necessary to insure the device is returned to its initial specifications are not available. Staffing and supervision are often not adequate to insure that a quality system is in place for the reprocessing activity. It is for these reasons that the IAHCSMM discourages the practice of healthcare facilities becoming involved in the reprocessing of single-use medical devices and does not recommend it.

However, the IAHCSMM recognizes that due to the constant reductions in reimbursement, many healthcare facilities have been forced to reduce expenses without compromising quality. One cost-saving alternative some facilities have chosen is the reprocessing of specific disposables by a third party reprocessor. Of course, every healthcare facility needs to assess its own situation to determine if the cost saving potential is worth the additional risk incurred.

Should a healthcare facility opt for third party reprocessing, it is the position of the IAHCSMM that the reprocessing company selected shall have completed registration with the Food and Drug Administration (FDA). Other criteria that users might want to require of a third party reprocessor include:

- The ability to track the medical device through the various stages of reprocessing,
- Written policies and procedures for cleaning, packaging, and sterilization,
- Documentation available to demonstrate procedures are being properly followed,
- Documentation of the training and/or certification of the staff, Insurance policies with appropriate liability coverage,
- A willingness to provide facility tours for potential customers,
- Demonstration that the waste from the healthcare facility is properly disposed of according to local, State, and Federal regulations.

The IAHCSMM also considers the decision whether or not to reprocess a single-use medical device, or use the services of a third party reprocessor, to be the responsibility of an appointed committee including administration, risk management, infection control, central service, and other appropriate departments of the facility."

Since that May meeting and the presentation of their Position Statement, the IAHCSMM has walked the walk, and talked the talk on Reuse. When the FDA responded to comments gathered from the conference with their Proposed Strategy on Reuse of Single Use Devices, the IAHCSMM reiterated their position and provided additional rationale for the fact that they considered the reprocessing of single-use devices (SUD's) in healthcare facilities to be a serious patient safety issue. Among their comments in response to the FDA Proposed Strategy was the following rationale for the need for FDA regulation of reprocessing of SUD's in healthcare facilities:

- It is estimated that over 50 percent of healthcare facilities are reprocessing SUD's with limited accountability, using reprocessing procedures that may or may not be adequate.
- Performance standards for sterile processing vary from one institution to another, and are not necessarily based on good science. This was described by one of our members in this way: "All healthcare facilities are not created equal . . . we have no one way or set of guidelines to reprocess specific items." The majority of

healthcare facilities rely on manufacturers' recommendations to establish their reprocessing protocols. Obviously, SUD's have no reprocessing instructions. There is little or no information provided by the original equipment manufacturer (OEM) regarding the materiels used in the manufacture of the device. There are no disassembly or reassembly instructions. Also lacking is information on the compatibility of cleaning and sterilization agents. All of this must be established in order to properly reprocess the device, and it is often beyond the capability of the sterile processing staff.

• Consensus standards, such as those developed by the Association for the Advancement of Medical Instrumentation (AAMI) are available to healthcare facilities, but they are voluntary standards. Only the State of New Jersey mandates that AAMI Recommended Practices be followed and inspects to insure compliance.

• Another concern is the lack in most of our healthcare sterile processing departments of a manufacturer's type quality system that identifies all the critical aspects of the reprocessing function, puts controls in place, and creates a process that is completely reproducible from beginning to end. There is an AAMI Working Group currently developing a Technical Information Report which will address the requirements of such a quality system for possible implementation in our healthcare facilities, but at present there is a great deal of misunderstanding of what would constitute an acceptable quality system for the reprocessing of a SUD.

Further rationale for the IAHCSMM position can be found in the ECRI document, Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions. ECRI, a nonprofit health services research agency, provides information and technical assistance to the healthcare community to support safe and cost effective patient care. Chapter 8 of this report is entitled, Developing, Testing, and Validating a Reprocessing Protocol. "To ensure that the product is consistently safe, ECRI advises healthcare organizations to follow procedures similar in spirit, if not in detail, to those outlined in FDA's Good Manufacturing Practices (GMP's) and to determine whether its third party reprocessors follow such procedures." It then discusses each stage of the reprocessing function for single-use devices: Cleaning, Functional Testing and Inspection, Reconditioning, Sterilization, Process Tracking, and how to test and validate the protocols.

A look at just the first function, Cleaning, underscores the IAHCSMM position. The ECRI document recommends,

• "For critical devices, it is advisable that pyrogen-free water (e.g. filtered or sterile water labeled as pyrogen-free) be used for cleaning and rinsing to insure that the pyrogen levels are acceptably low. Pyrogen levels of reprocessed devices should be no higher than levels found on new devices, unless standards or test results demonstrate that the levels present are safe."

This is not a Recommended Practice for reusable medical devices and could therefore be easily missed by a Central Service Department.

• "The cleaning procedure should illustrate the disassembly of devices to be disassembled (and reassembled), if appropriate, and washing methods. Detergents to be used should be specified, as well as their recommended dilution, water temperature, and duration of each step. Tools or instruments necessary for disassembly and cleaning should be listed in the procedure. For automated systems, the process to be used should be fully defined (e.g. times, temperatures, solutions). Material compatibility determines what agents can be used."

For reusable medical devices, this responsibility rests with the manufacturer, as described in the FDA document, Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: For Reviewer Guidance. Obviously, this information is not normally provided by the manufacturers of SUDs, and would have to be acquired through testing.

• "Ensure that plastic materials are compatible with the cleaning agents used. (Check with the agent manufacturer)"

This is problematic for a Central Service department. As described in AAMI TIR No. 12-1994 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers, "There are over 20 generic families of polymeric materials used in the manufacture of medical devices. These polymer families vary greatly in chemical formulation and will react differently to various chemicals, disinfectants, and sterilizing agents. While one type of sterilant or sterilization process might be compatible with a particular polymer, another could attack the polymer." The expertise and testing capability required to provide the assurance recommended is beyond that available in the majority of Central Service departments.

• "Use ultrasonic cleaners after manual washing to help remove soil in hard-to-reach areas on devices."

Equipment varies in Central Service departments dependent on budgetary constraints. Not every facility has an ultrasonic cleaner.

It is safe to say that if we were to expound upon each of the remaining reprocessing stages, Functional Testing and Inspection, Reconditioning, Sterilization, and Process Tracking, we would undoubtedly find that ECRI recommends "some differences, reflecting more closely controlled manufacturer procedures."

For Central Service departments, how to test and validate protocols is probably the least understood stage of the reprocessing function recommended by ECRI for single-use devices. Currently, process validation is not included in AAMI's recommended practices for healthcare facilities, and as a result, there is wide variation in how it is performed. This is an essential part of the process, so there is good reason for concern that this is not being done properly in many healthcare facilities.

The IAHCSMM offered comments and suggestions on the other sections of the Proposed Strategy, basically agreeing with the approach the FDA was taking. The IAHCSMM opinion was that it was a good strategy to develop a device categorization system and base regulation on the level of risk presented by reprocessing and reusing SUDs.

On April 5, 2000, the IAHCSMM again responded to the request of the FDA and submitted comments and suggestions on the newly released Draft FDA Guidance on Reprocessing Single-Use Devices and Enforcement Strategy. Because our position remained the same regarding reprocessing SUD's in healthcare facilities, and because we continued to support regulation, we considered the timetables offered for the start of regulation to be reasonable. We understood the rationale of phasing in the regulation and were in agreement with the 6-month, 12-month and 18-month plan for high, moderate and low risk categories.

The IAHCSMM is well aware of the outreach effort that will be required to educate healthcare Central Service professionals when the final Guidance documents become effective. From the onset of our participation in this project in May 1999 until now, the IAHCSMM has offered to be of assistance to the limit of our resources, in any manner possible, to resolve the dilemma of the reuse of SUDs. As stated previously, the IAHCSMM's only agenda is the safety of the patient and the delivery of quality patient care.

Senator COLLINS. Mr. Feltner, we heard from Ms. Torrente very disturbing statistics. She has illustrated one study where she suggests that almost half of reprocessed single-use biopsy forceps were contaminated. Now I am going to ask her the basis for that. Who did the study? How wide reaching it was? But I want you to respond to it because that is obviously troubling. It is obviously very disturbing. First, Mr. Torrente, could you tell us more about that study?

Ms. TORRENTE. Yes.

Senator COLLINS. How was it conducted, by whom?

Ms. TORRENTE. Senator Collins, this is a combination of eight studies. In total, over 100 devices were studied. In no study was the sterility better than 45 percent. But cumulatively it was only 49.4 percent unsterile. The basis of the problem, as I said, this is the biopsy forceps, 240 centimeters long. This end is the end that inserts into the patient. And there is a long lumen that goes through the device. Feces and other patient material can get sucked into that lumen.

The reprocessors say they test this every time. All they can test is this point right here. A proper sterility test would destroy the device. It involves cutting it into about 20 centimeter segments so that you can tell if there is a lack of sterility here. You could never tell that by testing this whole thing if the problem is in the center. That is the testing we did. It is USP approved testing. The devices were taken off the shelf by original manufacturers. Some of the studies were done in-house by the manufacturers. Most were sent off to independent laboratories for testing.

Senator COLLINS. Mr. Feltner, could you respond to that study? Do you think it has validity? Is it flawed? It is an alarming study and I would like to hear your response?

Mr. FELTNER. Well, there are several comments I would like to make. First of all, you know, we certainly would share the concern of any product that did not meet standards and sterility is fundamental, you know, for all medical devices. However, one thing that was missed, and we can only talk about the end of the device, there is a thing that Ms. Cofiell is well aware of and really got very close to explaining it in detail, and that is validation.

FDA requires that a manufacturer have a validated process for sterility and cleaning. Now, validation is setting up a process that will give you repeatable results. Ms. Torrente talks about the various tests that were made in house and so forth. I think you will find on page 16 of the GAO report that GAO stated that similar alleged events were found to be inaccurate or incorrect. I cannot address this because we do not have it.

To say, though, that she—in part of her presentation, she indicated that the standards of sterility were different for manufacturers of new devices and reprocessed. This is totally inaccurate. The standards are the same. When FDA inspects a reprocessor, the standards of SAL ten to the minus six or one in a million is the same standard they check and you must have a validated process for that sterilization process.

So I cannot comment on these because we do not have all the data. I did see some indication that a lot of this was done in house and the samples were quite small, but we share the concern. I think the validation speaks for itself and I think Ms. Cofiell would back that up.

Senator COLLINS. Ms. Torrente, the GAO found that some devices could be safely reprocessed and others could not. Do you agree with that or is your position that in no instance should a device that is labeled as single use be reprocessed?

Ms. TORRENTE. That is an excellent question, Senator Collins. In fact, we have never asked for a ban on reprocessing for just that reason. There may be devices that despite they are designed for single use, someone may be able to prove that they can reprocess them. We honestly believe our devices cannot be reprocessed.

If a device can be safely and effectively reprocessed, it be should proven to the FDA. The FDA should approve the device and then it can be sold and at that point we will have a product that is FDA approved and safe and effective for patients. Prior to that, a GAO study or any other study that does not meet an FDA standard of safety and effectiveness is not enough to convince me that a product can be reprocessed.

Senator COLLINS. Thank you, Mr. Chairman.

The CHAIRMAN. Well, thank you for your excellent help. Appreciate it very much. Ms. Torrente, today devices labeled as single-use essentially mean "not proven to be reusable." How could Congress and the FDA reform the device labeling system to more accurately reflect device capabilities and capacities?

Ms. TORRENTE. Mr. Chairman, I am really glad that you ask that because there have been a couple of comments about the label. And I think it goes to the core of what a single-use device is. Single-

use devices are not devices that are made and then we think about how do you label them. They are designed from the very beginning, from the blackboard, they are designed to be single use. Single-use devices in some cases like balloon catheters that Senator Frisk discussed are a medical innovation that would not have been possible without plastics and intricate technologies.

Before single-use devices, before these intricate pieces were available, patients had to have open procedures. Coronary bypass surgery, which would involve a five to 7 day recovery period for the patient, now we can go into the patient with a minimally invasive method through the leg and open a blocked artery. The tradeoff for that is you cannot clean the device. It is a pretty good tradeoff when the patient gets to go home the next day. That is what a single-use device means. There are some devices that come in two flavors, if you will, single use and reusable.

One is a stapler used for gastrointestinal, appendicitis, those sorts of procedures. A reusable stapler, and I do not have one, is a large sort of clunky, stainless steel device. It comes apart into three pieces that is easily accessed for cleaning. There is a market for that device because hospitals want to reuse and save resources.

There are other hospitals that want a single-use product. They want to be able to know that they do not have to worry about the cleaning; they can throw it away. And so a different device is manufactured. This is a single-use stapler. It is not stainless steel. In fact, it is plastic and aluminum. It cannot withstand sterilization. The part that actually makes the staple, instead of being made of stainless steel that uniformly forms a staple every time over and over, is plastic. After repeated use, it will deform. The staples will not form the same way anymore.

The advantage is it is much cheaper and it can be thrown out after one use in one patient. So the single-use label means a lot. In cases where reusable can be made, it is made, and there is a market for it. In cases where it cannot, like balloon angioplasty, it is a medical innovation that advances science.

The CHAIRMAN. Thank you.

Mr. FELTNER. Senator, may I comment on that?

The CHAIRMAN. Yes, please, Mr. Feltner.

Mr. FELTNER. I think there is one issue here that must be addressed and that is third-party reprocessors, commercial reprocessors, do a very small amount of the number of medical devices used in the United States. We just spent a long time talking about staplers. No AMDR company reprocesses staplers. In fact, on the list of most reprocessed devices, there is not an AMDR company that reprocesses 30 percent of those categories and in some cases 40 percent of those categories.

So we agree that not every device should be reprocessed. We are in total agreement. We do not reprocess every device. We only reprocess devices that can be validated for cleaning, validated for sterility, and functionally tested to show that they are capable of doing their job. So we do not want you to be mislead that this is a willy-nilly industry that is out there reprocessing everything. And let us not talk about how one product is made specifically as a disposable item. The doctor here just gave an example of how the very same item came to him with two different labels. So honesty—we

need to be forthright here in how we address this if we are going to really do our job and be concerned about the industry and patient safety.

The CHAIRMAN. Thank you. Dr. Clough, the GAO reported that it is difficult to access the validity of their findings because the response rates for their surveys of hospitals were so low. Only one survey had a response rate greater than 50 percent. Why is there such a low response rate from hospitals to questions on reprocessing, and are they afraid to admit to the practice?

Dr. CLOUGH. Well, that is a very interesting question, Senator Jeffords, and unfortunately I cannot talk for all hospitals, but I would believe that our hospital and our system of hospitals would respond to any kind of reasonable questioning from the GAO, and we have met with the GAO from time to time to try and help them deal with whatever issue it is that they are examining. Why some hospitals would not respond to a GAO survey I do not know. I think there may be some concern about liability there and especially if they have some data that they do not want to show, but I know that in our setting, the items that we reprocess, and we do reprocess certain materials, as I have mentioned before, which perform extremely well, and we have published the data.

The CHAIRMAN. Ms. Cofiell, are you able to clearly establish how many times a single-use device has been reprocessed and reused?

Ms. COFIELL. Am I? Would you repeat that, please?

The CHAIRMAN. Are you able to clearly establish how many times a single-use device has been reprocessed and reused?

Ms. COFIELL. You mean in the hospital scenario?

The CHAIRMAN. Yes.

Ms. COFIELL. There are tracking mechanisms. There are ways. I know that, in fact, I think, doctor, you are probably better able to answer this than I am. We are not in favor of reprocessing in the hospitals so we probably have a different viewpoint. And I must say that we have no difficulty with reprocessing, as you said, Mr. Feltner, that is able to be validated, which I am sure that Dr. Clough is doing, because what is available to Dr. Clough at the Cleveland Clinic might be available at Duke or it might be available at Pennsylvania Hospital maybe, but our association is basically representing the average hospital. Out of that 6,000 figure that we talk about, there are not many Cleveland Clinics and there are not many Dukes, and they have available to them laboratories, test facilities, equipment, that is not in the average hospital.

So I may be going a little astray from the question that you asked me. Yes, I am sure that you can track it if you have the equipment, the expertise, the time. The cutbacks that have come financially to hospitals have caused havoc in central service departments. Many of them are left without directors. Some of them are reporting the director is let go because of the money that they pay that they want to save, and they put the department in many cases under someone who is not even familiar with sterile processing.

So I think when you take the hospital situation that I am talking about where you are talking about just the average U.S. hospital out there, struggling with cutbacks in staffing, budgetary constraints that do not allow them to purchase additional equipment that they could use to do some of these more sophisticated things,

that is our concern and why we favor FDA regulation because we do not know what they are doing and how they are doing it.

Most of them just have standard hospital reprocessing equipment made for reusable devices, not made for the sophisticated work that some of the other, you know, better monied hospitals can afford.

The CHAIRMAN. Dr. Clough.

Dr. CLOUGH. Well, I think that much of what Ms. Cofiell said is correct, but I would say also that the Cleveland Clinic while we do reprocess catheters like this one here, we also use the third-party reprocessors for many instruments that we reprocess, and these selections are made on an individual basis by our quality management group and we use the method that works the best for the given situation for us.

So I think—and many devices that are reprocessed in some hospitals we do not reprocess, and we do not believe they should be reprocessed, and one is the biopsy catheter which is shown, which Ms. Torrente has shown. There are some instruments that are just too hard to clean. They were not made to be used more than once, but many of the devices are made exactly the same as they were back in the days when you reprocessed everything. The orthopedic saws is a perfect example of that. And if you look at these things, they even have the same catalogue number as they did back in the days when they came to you unsterile for the first use and you had to process them. So it was not a question of reprocessing. Then it was a question of processing in the first place.

So it is a mixed bag and it has to be done carefully and with judgment and regard for patient safety, which is the big issue that we are all concerned about.

The CHAIRMAN. Thank you. Mr. Feltner, do you support an FDA regulatory structure that improves oversight of reprocessing, if it also draws resources away from getting new breakthrough products to market?

Mr. FELTNER. We do agree with FDA's move to have more stringent regulation. In fact, AMDR and the formation went to FDA unsolicited and asked for increased regulation because we do have concern that there may be people who might get into the industry without full information of it. But I do not believe that we would have to share that resource. I can see no reason why we would take resources away from breakthrough devices simply because of regulation of reprocessors.

The CHAIRMAN. Ms. Torrente, the cost of health care is skyrocketing. Individuals in Vermont and across the country are seeing health insurance premiums increase as much as 20 to 30 percent this year. These increases are attributable to several sources, including the introduction of new technologies into the health care system. Do you disagree that hospitals could practice proper reprocessing in order to keep costs down or within the reach of the average American consumer?

Ms. TORRENTE. Senator Jeffords, I believe that if reprocessing can be done to FDA standards and be FDA approved and if it can still be done inexpensively that way and save health care dollars without putting one more patient at jeopardy, then, yes, it is a viable option. If, on the other hand, it is going to be done, as we heard across this table, Mr. Feltner said the three companies, part of his

association, do not reprocess this, yet it is on FDA's list of frequently reprocessed devices so somebody does.

Dr. Clough said that they do not reprocess biopsy forceps. Mr. Feltner's companies do. So this lack of oversight sort of leaves every reprocessor out there to decide and every hospital to decide what is good, what is safe, what is not. This is FDA's job. We need FDA to be doing its job. If these devices cannot pass FDA's standards, then they are not safe and they cannot save health care dollars because they will injure and infect patients.

The CHAIRMAN. Mr. Feltner, can you tell us how many third-party reprocessors currently operate within the United States?

Mr. FELTNER. I would not have that information. Everyone in the United States knows of AMDR as a professional organization for commercial reprocessors. Everyone is invited to join if they can meet the standards. Everyone that we know of we have invited. There are medical device manufacturers that we do not know of as well because we would not have any way of knowing everybody that manufactured or everybody that reprocessed product.

I would like to—I think it would be of great interest—and just for one moment to address something that I think is extremely important in this, senator, and that is patient benefit. So many times we hear that there is no benefit to the patient in reprocessing, that the cost is not passed on, and, of course, we have learned today that in some cases the savings is passed on. But it was brought up earlier with Dr. Feigal a concern about medical errors. And this was addressed in a hearing here in February concerning medical errors and one of your congressional colleagues commented on this and that he felt that the medical errors were not caused by the health care provider being less experienced or less well trained or less caring, but he thought that the high cost of medicine causing hospitals to cut staff, and I have not been in a hospital in the last 3 years who has not been through one or two rounds of personnel cuts, and I am talking about nursing personnel cuts because they cannot meet budget. When you cannot meet budget and you cut nursing staff, you have high levels of stress according to your colleague and this causes medical errors.

The cost of health care is a crisis and somebody must do something about it. We are all part of the problem. We should all be part of the solution. The savings can be redirected to staffing which would increase the standard of medical care, not lower it. This could be for updated equipment, for serving indigent patients. It would put less materials in the landfills. We put 12½ million tons of medical waste in our landfills everyday, throwing away hundreds of products that cost hundreds of dollars that, as the doctor said, are the same products he bought last year as reusable. This is insanity. We need help.

The CHAIRMAN. What was that figure again?

Mr. FELTNER. 12½ million tons per day is what I have read medical waste goes into our landfill.

The CHAIRMAN. Dr. Clough, how much do hospitals save by reprocessing single-use devices?

Dr. CLOUGH. It depends on the device. In my testimony, I gave some figures with respect to this as a radiofrequency ablation catheter. The cost of that catheter is $1,240. These catheters can be

used up to five times safely. We have got the data that proves that. And so that reduces that by a factor of not five because it costs something to do the reprocessing, but it is a considerable savings. And there are thousands of these procedures done every year using three to six catheters for each procedure. So the savings can be considerable depending on what you are doing and what the procedure is that you are talking about.

In the orthopedic saw case, the cost savings is much less. The blades cost only a few hundred dollars. And reprocessing costs makes them cost almost half the price for the reused one as for the new one. And they can only be used about three times because after that, they get dull and you cannot use them anymore. So it is very different and it depends on the mix of procedures that you are doing and the volume.

The CHAIRMAN. Well, thank you. Ms. Cofiell, from the perspective of central service and material management, how much money is saved by reprocessing single-use devices?

Ms. COFIELL. I really do not have a figure for that, senator. I really do not know.

Ms. TORRENTE. Senator Jeffords.

The CHAIRMAN. Yes.

Ms. TORRENTE. I think that I mentioned this when you were not in the room. There is a woman in the audience named Georgia Abernathy. Ms Abernathy's mother was injured in February by a device, and I think this is important to the cost issue. Ms. Abernathy's mother was having a kidney stone removed and it is a minimally invasive procedure where a small device is put into the patient, grabs the stone, and then comes out. Because the device had been reprocessed over and over, the little basket on the end had fatigued from overuse and it broke inside Ms. Abernathy's mother.

She has since had to have another procedure. They had to do an emergency there to remove the device. She has since had to have another procedure because of complications. Those are costs. Those are costs of reprocessing. The most interesting thing is those are not regulated as part of the costs because Ms. Abernathy had to go to tremendous efforts to find out that the device was reprocessed and the injury still 4 months later has not been reported to FDA. So, of course, reprocessing has no patient injuries. They are not being reported and, of course, it is cheap because we are not including these two other surgeries that have had to happen. We need to consider the full cost before we start talking about patient benefit from savings.

The CHAIRMAN. Well, thank you all. Does anyone have a desire to make a final comment to correct something or to enlighten us further? Ah, I am pleased that the answer is no, and I want to thank you. This has been extremely helpful and I appreciate the time and effort you all put into your testimony and answering the questions, and we reserve the right to keep bugging you.

[Additional statements and material supplied fort the record follows:]

PREPARED STATEMENT OF LARRY GIBBONS, VICE PRESIDENT OF QUALITY ASSURANCE AND REGULATORY AFFAIRS TYCO HEALTHCARE

Mr. Chairman, thank you for this opportunity to provide the Committee with important information needed to correct an erroneous impression left by the recent General Accounting Office report on single-use medical devices. In the opening paragraph of this report, GAO attempts to characterize the broad range of single-use devices subjected to reprocessing:

"Some reprocessed devices are relatively simple items for external use, such as sequential compression devices (inflatable sleeves to improve blood circulation), while others are complex and invasive, such as catheters that are inserted into the heart to monitor cardiac functioning." (Emphasis added)

The unfortunate effect of this unsubstantiated statement is to leave casual readers of the GAO report with the impression that sequential compression devices can be simply and safely reprocessed. As the Vice President of Quality Assurance and Regulatory Affairs for Tyco Healthcare, the company that manufactures the Deep Vein Thrombosis (DVT) compression device, I would like to specify the public health risks associated with reprocessing this "relatively simple item for external use."

At the outset, it is incorrect to equate invasiveness and complexity, and it is equally incorrect to assume a correlation between either one and the relative safety of reprocessing. Each single-use medical device must be evaluated in its own right, taking into account its individual design specifications, materials, and intended use. The risks associated with reprocessing and reuse of a compression sleeve are significant. The FDA should be concerned about cross contamination, patient infection, and device malfunction from the reprocessing of single-use medical devices.

As stated in the GAO report, the FDA is responsible for ensuring the safety and effectiveness of all medical devices sold in the United States, regardless of whether the device is an external item, such as a bandage, or a more complex medical device, like an artificial heart. Just as it is clearly an unacceptable medical practice to reuse a bandage, so should the FDA, Congress and Public similarly regard the reuse of a DVT compression sleeve.

A DVT Compression Sleeve may cover the leg from the ankle to knee, or as is most common, from the ankle to the thigh. For FDA regulatory purposes, it is a Class 11, non-exempt device. It is applied most often to bed-bound surgical patients as a precaution against the development of deep vein thrombosis, or "blood clots." The occurrence of DVT can be a life-threatening medical emergency. It is a condition that is wisely prevented with a compression sleeve, as opposed to treating it as a major complication during or following hospitalization.

The efficacy of the DVT Compression Sleeve results from a design that took many years of engineering investigation and manufacturing development. It is a complex device consisting of multiple air chambers that apply compression at various points on the leg. To enhance patient comfort, the inner surface of the compression sleeve is coated with a cotton-like material. These sleeves are typically worn 24 hours a day during the patient's period of immobilization.

Use by one patient during his or her hospitalization is considered a "single-use" application. Upon the patient's discharge from the hospital, the device should be discarded. Unfortunately, reprocessors have enticed hospitals to view DVT Compression Sleeves as a cost-saving target through repeated use on multiple patients, although the savings to the patient or the hospital are minuscule relative to the risk inflicted on the patient.

The most prevalent risk associated with reuse of compression sleeves from repeated use on multiple patients is cross contamination and subsequent patient infection. Twenty-four hour application over the course of several days subjects the compression sleeve to numerous bodily fluids, such as sweat, urine, and feces. The amount of soiling accumulated on a compression sleeve is similar to the amount of soiling that would accumulate on bed linens if left unchanged during the patient's hospitalization. This contamination is then compounded because the compression sleeve is normally placed in a bin with other contaminated products for shipment to the reprocessor.

Unlike bed linens, DVT Compression Sleeves are not designed for cleaning and reuse. Bed linens are cleaned on a daily basis using industrial washers and powerful anti-microbial detergents. By contrast, reprocessors attempt to clean compression sleeves by wiping them down with a cleaning solution and subjecting them to ETO gas. The cleaning process does not penetrate or saturate all portions of the sleeve, and there is no rinsing out of the cleaning chemicals or organic material.

The result is predictable. In fact, independent testing of reprocessed compression sleeve samples has shown a high incidence of contamination. Moreover, this limited cleaning process increases the probability that the compression sleeve will not func-

tion properly. As a result, the standards and specifications an original equipment manufacturer delivers with a functional single use compression sleeve are compromised with reprocessing. On the other hand, if the reprocessor were to attempt to ensure the cleanliness and sterility of the compression sleeve by subjecting it to the cleaning process used for bed sheets, the result would, in most cases, produce a product that would not function properly.

As a preventative measure, the single use DVT Compression Sleeve is designed to save money for the healthcare system by preventing the occurrence of deep vein thrombosis, often seen in the immobile, elderly and severely ill medical and surgical patients. A lack of understanding of the sleeve's design and application has erroneously led cost-conscious hospital administrators to believe that money can be saved through reprocessing. Unfortunately, this is done without regard for the risks of cross contamination and malfunction. It is also done without the patient's consent. If the choice of having a reprocessed compression sleeve or a new one is provided to patients or their families, given the information just presented, which option do you believe they would choose?

We encourage Congress and the FDA to begin pursuing steps that will properly regulate the reprocessing of single-use items, regardless of whether the device is considered simple or complex. Thank you for your attention and concern regarding this important patient safety issue.

Prepared Statement of the American College of Cardiology

Introduction

The North American Society of Pacing and Electrophysiology (NASPE) and the American College of Cardiology (ACC) appreciates the opportunity to submit a statement to the Committee on Health, Education, Labor and Pensions (HELP) about the safety and efficacy of using reprocessed electrophysiology (EP) catheters in patients. EP catheters are used in cardiology procedures such as electrophsyiology studies or cardiac ablations that are performed to diagnosis or treat patients with heart rhythm disorders. NASPE and the ACC commend the HELP Committee at drawing attention to this important Issue and for holding a forum to discuss the findings of the General Accounting Office (GAO) report "Little Available Evidence of Harm from Reuse, but Oversight Warranted".

Over the past several months there has been Much discussion, and unfortunately much factual distortion, about the reuse of certain medical devices. NASPE and the ACC's position focuses solely to the reuse of EP catheters and not the other medical devices under discussion. For more than 20 years, cardiovascular specialists have been safely using reprocessed EP catheters to treat their patients. The reuse of EP catheters, used in the diagnosis and treatment of heart rhythm disorders, has been proven safe, effective, and cost efficient.

The ACC and NASPE seek to promote optimal patient care through the dissemination of research and the continuing education of the cardiologist. These organizations also provide leadership in the development of standards and guidelines and the formulation of health care policy. The interest of these two organizations in the medical reuse debate grows out of concern for patient safety and the promotion of quality cardiovascular care for patients. Our members do not have any direct or indirect financial interest in the reuse of EP catheters. The involvement of NASPE and the ACC in this issue is rooted in scientific evidence. The ACC and NASPE have been working with the Food and Drug Administration (FDA) and believe that it has also taken an approach to the issue of medical device reuse that is based in science and out of concern for patient safety.

Summary:

NASPE and the ACC believe that the reprocessing and reuse of EP catheters is safe and that the FDA has issued a proposed strategy which when implemented will provide a scientific and risk-based approach to regulating the practice of reprocessing by hospitals and third-party reprocessors.

Reprocessing is safe. Reprocessing is a safe practice that hospitals and physicians have relied on for more than two decades. A significant body of peer-reviewed literature demonstrates that certain devices labeled as single-use can be safely and effectively reprocessed, including EP catheters used by cardiovascular specialists.

Neither the FDA nor the GAO has found reprocessing to be unsafe. The Food and Drug Administration (FDA)—the regulatory body which has primary responsibility for the safety of medical devices—has stated that it "has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single-use device from any source." The GAO's most recent report confirms that "hospital infection control experts at the Centers for Disease Control and Prevention

(CDC) told us that the evidence showed that single-use device (SUD) reprocessing was not a public health risk. CDC experts said they were not aware of patient illnesses caused by SUD reuse in the last decade and that the hospital infection surveillance systems they relied on would have uncovered the infections had they occurred."

The FDA is actively involved in regulating reprocessing. With the publication of FDA's proposed strategy to enhance regulation of reprocessed SUD's, the FDA has demonstrated a good faith effort to implement uniform reprocessing standards to insure patient safety. Currently, the FDA regulates third party reprocessors by their adherence to the Quality System Regulations (QSRs). Although NASPE and the ACC have taken issue with certain aspects of FDA's proposed strategy, both organizations are in complete support of FDA's efforts to bring uniformity to the practice and welcome the additional regulatory oversight. NASPE and the ACC will continue to work with the FDA to refine its regulation of reprocessed devices. NASPE and the ACC recommend Congress defer to the FDA on the Issue as the FDA continues to finalize and implement its regulations.

The single-use designation is a choice made by manufacturers. The "single-use" designation on a medical device is not a FDA requirement, but rather, a manufacturer's choice that has become widespread but may be used arbitrarily and without regard to the risk of the device to patients. NASPE and the ACC have asked the FDA to examine this issue and clarify this label designation.

NASPE and the ACC Agree with the GAO Report and Support the Continued Use of Reprocessed EP Catheters as Part of a Rational, Science-based Regulatory Framework to Insure Patient Safety. Years of clinical electrophysiology experience and a review of the medical literature indicate that using reprocessed EP catheters is a cost effective and safe practice which does not compromise, patient care. The GAO in their report to Congress, "Little Available Evidence of Harm from Reuse, but Oversight Warranted" frames the issue of risk as a "theoretical health risk" and indicates that the available "clinical evidence shows that some devices can be reprocessed safely". More specifically, NASPE and the ACC would like to draw the committee's attention to the GAO's examination of EP catheters.

The GAO states that *"EP catheters (devices inserted into the heart to measure and correct cardiac rhythm disorders) have been reprocessed for 20 years, even though all of them were approved for single use only. EP catheters are relatively easy to clean, (because they do not have long hollow tubes) sterilize and test. In addition, they are expensive (ranging from $100–$1,500) and several catheters could be used inn a typical EP procedure.*

The safety of reprocessing some types of devices, such as EP catheters, is supported by well-developed clinical literature. Studies have shown both that reprocessing procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of reprocessed SUD's. For example, several studies have documented the safe reprocessing and reuse of EP catheters. One study, of more than 14,000 EP procedures found that the overall rate of patient infections was very low, and slightly lower in clinical centers that reused EP catheters than in centers that used each catheter than in centers that used each catheter only once. A later study of 69 catheters used in 336 procedures concluded that carefully reprocessed one model of single-use catheters up to 5 times, posed no health risk to patients."

NASPE and the ACC believe the GAO has accurately and succinctly summarized the issue of EP catheter reuse. Attached, as an appendix to our statement is a summary of the peer reviewed medical literature related to EP catheter reuse as cited in the GAO report.

Electrophysiology Procedures

NASPE and the ACC's comments focus exclusively on the practice of EP catheter reuse and are based on years of clinical experience in performing EP Studies and cardiac ablations. Clinical cardiac EP studies are performed to diagnose and treat abnormal heart rhythms referred to as arrhythmias. Typically, three to six catheters are used during these procedures. Each catheter incorporates four to 20 platinum electrodes to record electrical signals or pace the heart. The standard EP catheters are solid nonluminal designs, which means they do not have a hollow inner core. Some catheters have special mechanisms used to deflect the tip to help guide the catheter to a specific target. Catheters with these deflection mechanisms are often used to deliver radiofrequency energy—a high frequency electrical current—to destroy a small amount of abnormal tissue on the lining of the heart that has been identified as the cause of a patient's abnormal heart rhythm. This curative technique is referred to as an arrhythmia ablation procedure.

The cost of catheters used to perform EP studies varies depending on the number of electrodes, steering mechanisms, or materials used for the particular model. Diag-

nostic catheters range in cost from $100 to more than $1,000. Deflectable catheters used for ablation of abnormal heart rhythms generally cost $400 to $800. Some advanced designs that provide feedback about the position and orientation of the catheter cost S2,000 to $3,000.

The first EP procedures were performed more than 30 years ago. EP catheters proved to be quite durable and appropriate for re-sterilization and reuse, as had been the practice for many surgical instruments. The obvious motives were to reduce cost and eliminate the waste of catheters that could be reused without compromising patient safety. The physicians who perform these studies have no direct or indirect personal financial incentives to reuse catheters, and there are ethical, medical, and legal reasons to avoid any practices that Would add material risk to EP studies. The cost of medical supplies is the responsibility of the hospital where the procedure is performed; however, physicians often consider it their responsibility to work with hospitals to make efficient use of supplies and reduce operating costs.

Arrhythmia ablation procedures typically take three to 10 hours to perform. In order to advance the EP catheters to the heart, tube-like sheaths are inserted into the arteries and veins to provide vascular access for EP catheters. The catheters are then inserted through the sheaths and advanced to the heart. The sheaths allow cardimuscular specialists to remove, exchange, or reinsert the EP catheters as needed during the procedure. Sometimes catheters—new or reprocessed—must be exchanged because they do not have the necessary configuration to reach a specific target in the heart, or because they have become less maneuverable during the course of the procedure. Sometimes several catheters are tried during a procedure before the optimal catheter is identified. Reprocessing allows the flexibility to use several catheters during an EP study safely and free of fiscal concerns.

In some cases the catheter is easily positioned at the target site and is subjected to very little manipulation. In more difficult cases a catheter may be removed and reinserted several times during the course of a procedure and is subjected to considerably more stress when extensive efforts are required to reach the target. Because the stresses that call be imposed on an individual catheter can vary considerably during a study, EP catheters are manufactured to be very durable.

It is their durability which makes them reprocessable. Regardless of the amount of stress imposed on a catheter during a study, each one Is careful, evaluated by the reprocessor to determine whether it is suitable for reuse.

The number of catheters used during an EP study can have a substantial impact on the cost of performing the study, but it does not change the level of reimbursement from Medicare or other third-party payors. When the cost of catheters exceeds the level of reimbursement, hospitals bear the loss.

Medical Device Reports

NASPE and the ACC are aware that there have been Medical Device Reports (MDRs) submitted to the FDA that contain information about three cases involving EP catheters. One case involved a reprocessed catheter. The other two occurred with new catheters labeled for single use. It is appropriate to emphasize that despite the reuse of hundreds of thousands of catheters, only one MDR has been submitted to the FDA that involved a reused catheter. The reports are summarized below:

- A new deflectable ablation catheter was being positioned in the right atrium when the catheter tip was noted to be detached and wedged in the coronary sinus. The patient was observed overnight and discharged the following day without any reported symptoms.
- A small fragment of the distal tip in proximity to the electrode side of a new catheter broke away and the fragment could not be located. Further details are not available.
- A reprocessed orthogonal EP catheter was used without incident until it was removed from the heart. The physician felt some resistance during removal of the catheter. A subsequent x-ray showed a small electrode fragment lodged in the wall of the right atrium. It was presumed that a single platinum electrode mounted on the surface of the catheter might have been compromised during reprocessing. The surgical consultant decided that removal of the fragment was not indicated and the patient remained free of symptoms.

We recognize, as does the GAO, that underreporting of medical device problems occurs with both reprocessed and new medical devices. We look forward to working with the FDA, original equipment manufactures and reprocessors to educate users of these devices the public health importance of submitting both mandatory and voluntary MDRs.

FDA's Proposed Strategy

The FDA has proposed a regulatory strategy to address the reuse of medical devices currently labeled for single use. This policy was developed in response to the concern that a device's performance, safety, specifications, or intended use might be

compromised during reprocessing procedures. These new guidelines would be applicable to both commercial reprocessors and hospitals that engage in these activities. NASM and the ACC strongly believe that it is the FDA's responsibility to provide oversight of medical device reprocessing which will ensure uniform standards to which third party reprocessors and hospitals would be accountable. One of the principle components of the FDA's strategy is to prioritize its enforcement activities based on the degree of risk posed by reprocessing "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" sets forth factors they will consider in categorizing a reprocessed device as high, moderate, or low risk, and includes a list of commonly-reprocessed SUDs and the degree of risk the FDA believes each type of device poses when reprocessed. The second draft guidance, entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," sets forth the FDA's priorities for enforcing various regulatory requirements, based on the categorization of a device. In this document the FDA has determined that all diagnostic and ablation catheters used in electrophysiology studies are high-risk devices because of their technical complexity, risk of infection. difficulty of sterilization, the risk levels of the electrophysiology studies, and the lack of recognized standards for re-sterilization. NASPE and the ACC submitted comments to the FDA questioning the placement of EP catheters in the high risk category because published studies indicated the risk of infection and the ability to re-sterilize EP catheters is not high. We also questioned the need for pre-market approval for reprocessed EP catheters because of EP catheters record of safe and effective reprocessing. NASPE and the ACC have also recommended to tile FDA that the "single use" designation chosen by manufacturers be examined and evaluated for its clinical significance. We understand that this is a relatively recent development by the OEM's and may be used arbitrarily at the OEM's discretion for financial reasons.

Impact of Reuse Policies on Physicians, Hospitals, and Patients

Most EP laboratories are staffed and administered by hospital employees. The cost of supplies and maintenance for EP laboratories is also paid from hospital budgets. The physicians' motive to reuse EP catheters has arisen from their experience that the catheters are durable and can be safely used for several procedures without posing an increased risk to the patient. As such, it would be a waste to discard EP catheters after a single use.

The risk to patients associated with reusing EP catheters is inconsequential relative to the overall risk of these procedures. The risk is, in fact, so low that it is difficult to quantify. Policies that prohibit or severely restrict the reuse of EP catheters will not have an impact on patient safety, but they will certainly increase the costs.

Informed Consent:

One of the concerns raised in this debate is the subject of informed consent—that is—that patients are not currently informed when reprocessed catheters are employed. Informed consent focuses on the issue of informing patients of substantive risks. Informed consent depends on whether the physician believes and knows that there is an appreciable risk to patients when electrophysiology catheters are reused. Physicians do not routinely obtain consent for the second use of a device that is labeled "reusable" because this is not associated with substantive risk. Moreover, physicians are not compelled to inform patients before using devices that have been the subject of a MDR or Warning Letter from the FDA. Physicians do not generally advise patients that medical devices are subject to recalls, nor do they exclude the possibility that devices used in the procedure could be recalled in the future. In these cases, informed consent is influenced by the physician's knowledge and judgment and level of risk relative to the inherent risk of the procedure. When informed consent is obtained for invasive procedures such as EP studies, the patient's decision must be made without duress or coercion. Patients must be informed about the nature and purpose of the procedure, the alternatives to proposed treatment, and the material risks and benefits of the procedure or its alternatives. Patients must also be given the opportunity to ask questions and receive understandable answers.

In the case of diagnostic or therapeutic electrophysiology studies the risk of a life-threatening or fatal complication is in the range of 1:1000. Certain other risks may be higher depending on the nature of the procedure. The risk of reusing EP catheters appears to be so low that no reasonable estimate has been identified. Relative to the overall risk of the procedure, the risk of reusing electrophysiology catheters is insignificant. NASPE and the ACC believe that requiring physicians to provide informed consent to patients when reprocessed EP catheters may be used is not necessary. Reprocessed EP catheters do not pose additional material risk to EP procedures and therefore there is no ethical reason why informed consent would be required. In fact, if at some point in the future, an appreciable risk were identified

with the use of reprocessed EP catheters, our members would abandon the practice of using reprocessed EP catheters.

Summary

NASPE and the ACC commend you, Mr. Chairman, and the other members of the Committee for looking at this issue in a fair and responsible manner. We support the position that reuse of EP catheters is a safe and cost-effective practice provided that these devices are cleaned, sterilized, and inspected in accordance with accepted standards of practice. NASPE and the ACC believe the GAO did an excellent job at providing all overview of the issue of medical device reprocessing. The GAO report clearly states that medical device reprocessing, specifically for EP catheters, can be done safely and without compromising patient care. The GAO report also indicates that medical device reprocessing provides a safe and reasonable method for hospitals to control costs.

Both organizations are working with the FDA to refine the proposed strategy that will be applied to reprocessing medical devices and to clarify the criteria for single-use labels. We urge Congress to defer to the FDA as it finalizes and implements the proposed regulatory strategy for the reuse of medical devices that is based on science and emphasizes public safety as the first priority. We firmly believe that no further congressional action is required at this time.

NASPE is a professional membership association comprised of 3,500 physicians, allied health professionals, and scientists committed to the research and treatment of patients with cardiac arrhythmias.

The ACC is a 24,000-member professional medical society whose mission is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, leadership in the development of standards and guidelines, and the formulation of health care policy.

APPENDIX

Review and Summary of Published Clinical Studies Regarding Electrophysiology Catheters

There are studies, all of which have been published in peer-reviewed scientific medical journals, which have evaluated the safety of reusing catheters for EP studies. All have found no evidence that the sterility of reprocessed catheters is a concern or that the incidence of infection is increased. The results of four clinical studies are summarized.

1. The results of a study of 12 medical centers were published in the medical journal Pacing and Clinical Electrophysiology in 1988. The study looked at the safety of reusing catheters. The incidence of infection related to a total of 14,640 EP procedures involving 48,075 catheter uses was reported. At three centers, catheters were automatically discarded after a single use. These centers carried out 1,245 EP procedures using 3,125 catheters. At the other nine centers, catheters were sterilized for reuse. There were 13,395 procedures using 44,950 catheters in the reuse group. The incidence of bacteremia (blood borne infection) and superficial skin infection at the site of catheter insertion is shown below.

Table 1: Incidence of Infection During EP Studies,

Group Single Use Catheters Bacteremia 1(0.03 percent) Superficial Skin 1(0.03 percent) 1,245 studies, 3,125 catheters

Reused Catheters 13,395 studies, 8(0.018 percent) 1(0.002 percent), 13,395 studies, 44,950 catheters

The authors of the study concluded that sterilization and reuse of the catheters employed in this study did not result in any increase in the risk of infection. They felt the catheters were sufficiently durable to be reused well in excess of five times, and that one-time use of such catheters appeared to be a medically unnecessary and expensive policy to adopt.

2. Similar results in a prospective study were published in the Journal of the American College of Cardiology in 1987. The study evaluated catheter reuse over a five-year period during which 178 catheters were used 1,576 times for 847 EP procedures. Detailed records of catheter testing and use were maintained. No complications were encountered during the study period.

All reused catheters functioned for cardiac pacing and recording of cardiac electrical signals. Surveillance cultures and biologic indicators revealed that adequate sterilization procedures were used. The authors concluded that EP catheters may be safely reused provided a thorough cleaning, testing and record-keeping system is instituted. They also concluded that the practice of reusing catheters would result in substantial cost savings to hospitals.

13. The studies mentioned above were conducted in patients undergoing diagnostic EP studies before the advent of deflectable catheters and arrhythmia ablation procedures. A study published in the Journal of the American College of Cardiology in 1993 prospectively investigated the time course of electrical, physical and me-

chanical changes in ablation catheters to determine the affect of reuse on safety and efficacy. The study included 69 ablation catheters made by a single manufacturer that were used in 336 procedures. Testing of physical integrity consisted of visual and stereoscopic (X30 magnification) examination of handle function, catheter shaft and the deflectable tip. Specific attention was paid to the ablation electrode attachment to the catheter shaft, and the abalation tip electrode was scrutinized for pitting. The electrical integrity of the catheters was measured by electrical resistance from the handle connector to the recording rings and to the tip electrode. Deflection and torque measurements were made to assess mechanical integrity.

During the course of this study 36 catheters (52 percent) were rejected at some point because of mechanical or electrical failure. Eighteen catheters were repeatedly sterilized and eleven of the catheters were used 10 or more times. The most common reasons for catheter rejection were tip electrode glue separation after an average of 43 uses and loss of deflection after an average of five uses. Electrical discontinuity was observed after an average of 10 uses. There was no significant decrease in catheter torquing ability that determines the steering responsiveness of the catheter. The medical records of 140 patients who had arrhythmia ablation procedures in this study revealed only one case (0.7 percent) of local infection at the insertion site that was treated effectively by antibiotics. There were no other complications.

The authors of the study concluded that the catheter model used in this study could be reused an average of five times. They recommended that after each use catheters be carefully examined under magnification with special attention to the tip electrode. They also recommended that the catheters be tested for deflection and electrical integrity after each use.

4. Another study published in the American Journal of Cardiology in 1994 looked at the effects of reprocessing on mechanical integrity, sterility, and chemical residuals. The study was part of an internal quality review process conducted by a hospital to establish and validate an institutional policy for reuse. A total of 12 commercially available catheters from two manufacturers were analyzed. Eleven of the catheters were randomly selected from the catheter inventory of the clinical EP laboratory after being used one to four times. They were manually cleaned, repackaged, and gas sterilized with ethlyene oxide. To assess the sterility of reused catheters, three were cut into two-inch segments, placed in bacterial culture media, and incubated for five days. Six of the catheters were analyzed for clinical residuals after as sterilization. Two catheters were examined for evidence of component failure. Visual inspection and microscopy were used to determine mechanical integrity of the catheter Surface, and x-ray inspection was performed to assess interior Structures.

The results showed no bacterial growth detected on any of the cultures, which indicated that reprocessed EP catheters are effectively sterilized. The chemical analysis demonstrated that the concentrations of ethylene oxide detected in extraction liquid exceeded standards established by the FDA. Microscopic examination of reprocessed catheters demonstrated inconsequential metal and fiber particulates on the catheter surface and at some electrode-catheter interfaces. The shaft of the catheters and the electrodes remained intact. There was no evidence of electrical discontinuity, and the integrity of internal Structures was confirmed by x-ray inspection.

The authors concluded that, with sterilization techniques frequently used by hospitals, the potential for chemical residual contamination might exist after sterilization with ethylene oxide. Based on these results the hospital changed its policy to single use. It should be noted that the hospital subsequently resumed multiple use of catheters that were reprocessed by a commercial vendor whose chemical residuals after reprocessing met FDA standards.

Prepared Statement of the National Consumers League

The National Consumers League (NCL) is a national, nonprofit, consumer advocacy organization founded in 1899 to represent consumers in the marketplace and workplace. NCL commends the Senate Health, Education, Labor, and Pensions (HELP) Committee, under the leadership of Chairman Jeffords and Senator Kennedy, for holding this hearing. As the Committee examines the complex issue of the reprocessing of devices labeled for single-use, we want to bring to your attention the important consumer implications of this issue.

NCL believes that Congress must do all that it can to assure that the Food and Drug Administration (FDA) is doing its job to protect public health. We believe that the HELP Committee is moving in the right direction as it investigates and oversees FDA's regulation of medical device reprocessing. The safety of medical device reprocessing must be the overriding concern of Congress, FDA, hospitals, and physicians.

Clearly, no amount of health care cost savings can be justified if safety is compromised.

In our view, the medical device reprocessing debate concerns two very different interests—the interests of consumers who expect safe health care practices and the interests of the medical device manufacturers who are working very hard to eliminate competition. First and foremost should be the interests of consumers. Through appropriate regulation, FDA must assure that medical device reprocessing is safe. Consumers should have confidence that when a reprocessed medical device is used in a procedure, it will perform as safely and effectively as it would on its first use. Consumers should be assured that they will not experience an infection or health complication or be harmed because a device was reprocessed.

Once it is determined, through sound science, that medical device reprocessing can be safely performed and is adequately regulated, then and only then should the cost savings that such a practice provides be considered. Faced with overwhelming cost pressures, hospitals are increasingly reducing staff and scaling back on the procedures they will perform. For many consumers, the result has been lower quality and less affordable health care. Measures that can help control health care costs must be encouraged but should never be considered if patient care is compromised.

As you know, medical device reprocessing is a practice aimed at reducing the significant costs associated with medical devices labeled as "single-use" or "disposable" by the manufacturer. We understand that many hospitals have been reprocessing "single-use" devices for years, and that a number of hospital and physician groups have sent letters to Congress expressing their confidence in the safety and effectiveness of reprocessed devices. The June 2000 General Accounting Office (GAO) report on reprocessing also gathered similar statements of widespread confidence in reprocessing.

FDA has a strong tradition of protecting the public health. As FDA reviews its regulatory approach for medical device reprocessing, we expect the agency to continue this strong tradition. The GAO Report is encouraging in its findings that properly performed reprocessing of certain devices has proven to be safe. As FDA moves forward from this Report, FDA should take a strong regulatory posture that is systematic, rooted in sound science, and based on risk.

However, when effectively applied and enforced, FDA's current regulatory regime affords consumers appropriate protection. FDA's Quality System Regulation (QSR), which governs the reprocessing of medical devices by third-parties, is similar to good manufacturing practice regulations and sets forth requirements designed to assure that reprocessed devices are clean, sterile, and functional. Through inspection, FDA must assure compliance with all of the QSR requirements, including process validation, acceptance activities, internal audits, personnel training, storage, and complaint handling. By requiring those engaged in the reprocessing of medical devices to withstand the scrutiny of FDA inspection, consumers can have adequate assurance that reprocessed medical devices are clean, sterile, and functional.

FDA is reviewing its policy to require premarket review of reprocessed medical devices. Premarket review can complement and reinforce the effectiveness of the existing QSR requirements. Because premarket review for new devices is necessarily different from premarket review for reprocessed devices, FDA is working to develop an appropriate risk-based premarket review scheme. That is of fundamental importance. Imposing a premarket review procedure on hospitals and third-party reprocessors simply because device manufacturers are demanding it for competitive reasons would be a waste of precious FDA resources, as well as an unconscionable loss of an opportunity to better protect public health. FDA must develop a premarket review scheme that reinforces the QSR's objectives of assuring that devices are clean, sterile, and functional. Public health protections, not industry competition, must be the guiding principle.

NCL also believes consumers deserve more information about the risks and benefits associated with all health practices, including procedures that involve using all types of devices, new and reprocessed. FDA should work with consumer and patient advocates to ensure that the messages patients receive are accurate and thorough. To that end, statutory requirements for providing informed consent—in consumer friendly language to assure that the patient understands—should be more broadly applied so that consumers may assess the relative risks of a procedure or a particular device. The FDA should require that all significant risks trigger an informed consent requirement. In this way, consumers will receive relevant information, communicated both orally and in writing in understandable language, and the information they receive will be put in its proper context with respect to their own health care regimen.

As mentioned, the issue of medical device reprocessing touches on two different interests: the interests of consumers and the interests of the medical device manu-

facturers. As the Committee studies the safety of medical device reprocessing, we urge you to take note of the strong opposition to reprocessing voiced by the manufacturers of "single-use" devices. You should be aware that the term "single-use" is a term that is chosen by the manufacturer of the device; it is not required by FDA. There is a clear economic incentive to label devices as single-use" in order to sell more devices.

As Congress considers the issue of medical device reprocessing, it should make sure that FDA puts in place a sound, science-based regulatory procedure for medical device reprocessing, which will protect the public health and assure consumers that the devices used in their health care are safe and effective and above all, will do no harm.

Prepared Statement of the American Society of Cataract and Refractive Surgery

Mr. Chairman, and members of the committee: The American Society of Cataract and Refractive Surgery (ASCRS) appreciates the opportunity to present testimony regarding the reuse of single-use devices (SUDs). ASCRS represents nearly 8,000 ophthalmologists in the United States and abroad who share a particular interest in cataract and refractive surgical care. ASCRS members perform the vast majority of the cataract and refractive procedures done annually in the United States.

ASCRS is concerned that the FDA is in the process of establishing an expensive bureaucracy to determine the best management for SUDs. The proposed strategy calls for evaluating each device as being at low, moderate or high risk for reuse and establishing appropriate penalties for abuse of the system. We are concerned that the proposed FDA plan does not indicate an evidence-based rationale for implementing the agency's proposed strategy on SUDs. Absent evidence-based literature, it would seem that the proposed strategy is either unnecessary or more cumbersome than needed.

Quite frankly, the intentional reuse of products designed for single-use only has been promulgated because of reduced reimbursement to hospitals, outpatient centers, and other facilities. Should the FDA have genuine concern that the reuse of SUDs are creating public harm, we believe that the incriminating data, if available, be made public and that adequate funds are made available to provider institutions for the express purpose of eliminating the reuse of SUDs.

Alternatively, many SUDs can be reused. It would be beneficial for the FDA to develop methods to use these devices efficiently and more than once in a safe and effective manner. With that approach, FDA could justify involvement in reducing costs of medical care while preserving public safety.

In addition, ASCRS would like to express support for statements included in the June 2000 General Accounting Office report on reprocessing questioning FDA's current single-use label designation. Specifically, ASCRS is concerned that FDA's approval requirements for SUDs are less extensive than those for reusable devices. Device manufacturers can save both time and resources by requesting a single-use label for a new device and by not seeking FDA approval for sterilization instructions. Reforms to FDA's process for designating a device as single-use are warranted to address this concern.

Again, ASCRS would like to thank the committee for this opportunity to testify on the issue of reprocessing single-use medical devices. Please feel free to contact Pam Johnson, ASCRS Manager of Regulatory Affairs, at (703) 591-2220 or by e-mail at p.johnson&ascrs.org with any questions regarding these comments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 31 2000

The Honorable James M. Jeffords
Chairman
Committee on Health, Education,
Labor, and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Mr. Chairman:

This is in response to your letter of July 12, 2000, requesting answers from the Food and Drug Administration (FDA or the Agency) to questions about the reuse of single-use medical devices (SUDs), in follow-up to the recent hearing held by the Committee. Thank you for your continued interest in this issue.

Each question submitted by Committee Members will be restated, followed by our response.

Questions Submitted by Chairman Jeffords:

1. **Do you anticipate that the FDA's new review of pre-market applications for reprocessed single-use devices will slow the approvals of new, breakthrough devices?**

FDA's Center for Devices and Radiological Health (CDRH or the Center) prioritizes the review of new breakthrough devices, and there are relatively few such devices in a given year. Therefore, we do not anticipate that the reviews for these types of devices will be slowed by an increase in product review workload for SUDs that are reused. The Center has requested funds in Fiscal Year 2001 to cover our anticipated increase in premarket submissions for reused SUDs, as well as other activities related to reuse of SUDs. This request, however, has a degree of uncertainty. If our original estimates with respect to the reuse workload are substantially lower than our actual experience, we will work toward prioritizing our efforts in this area so as not to adversely affect bringing important new technology to the patient's bedside.

2. **How many site inspections of third-party reprocessing facilities did FDA conduct in 1999 and 2000? How many warning letters or other regulatory actions followed these inspections? What were some of the problems that the FDA inspectors uncovered?**

In order to respond to this question, we must consult with all of our District Offices. We will forward a response to the Committee as soon as the information is available.

3. **According to the GAO, many health care professionals believe manufacturers market devices as "single-use" because they have an economic incentive to do so and realize greater profits. Do you anticipate reviewing the regulatory requirements for labeling devices as "single-use" versus**

"reusable"? Do you envision the need for another type of device labeling, such as a distinction between "proven safe for one use only" and "not proven to be reusable"?

FDA's examination of the regulatory issues surrounding reuse of SUDs has brought attention to concerns over the labeling of those devices. At this time, the Agency does not plan to issue additional regulations for labeling of single-use or reusable devices. However, FDA has identified as a top priority issue the need to clearly articulate the Agency's requirements for labeling of SUDs and reprocessed SUDs. We anticipate convening a forum that will include original equipment manufacturers, reprocessors, health care professionals and hospitals, to address concerns with the Agency's labeling requirements and industry's current labeling practices. FDA will take action if this reexamination indicates a need for additional guidance or a new regulation.

Questions Submitted by Senator Frist:

1. When you testified before the House Commerce Committee in February of this year on the reuse of single use devices, you noted that in the late 1970's the FDA wrote a letter strongly discouraging the practice reprocessing and telling the hospitals they they accepted complete liability if they did this. I believe it is currently unclear who would be held liable, the original manufacture, the preprocessor, the health care facility which uses the device, or the physician who elects to use the device. While I realize that the FDA may not have expertise when it comes to medical malpractice issues, is the FDA aware of who should be held liable if a reprocessed single use medical device fails and causes injury to the patient?

We could not identify any FDA communication as you described telling hospitals that they "accepted complete liability" for reprocessing. However, on November 11, 1977, FDA issued the enclosed Compliance Policy Guide (CPG) 300.500 Reuse of Medical Disposable Devices. It states, " . . .any institution or practitioner who resterilizes and/or reuses a disposable medical device must bear full responsibility for its safety and effectiveness." The facts and laws pertaining to that situation determine legal liability in that situation. In any case, such a determination is outside FDA's authority.

2. In FDA's Draft Guidance issued on February 8, 2000, two types of pre-market submissions requirements are called for - a pre-market notification called a 510(k) and a pre-market application. As you are aware the average time of an approval of a 510(k) is, I think a little over 100 days. In addition to the submission, the reprocessor would also have to develop a protocol for reprocessing the single use device, they would have to validate the protocols before the application is submitted. From start to finish this process could take a great deal of time. This is notable because a great number of devices are on the market for a short amount of time, maybe less than two years, before they are updated and change due to technological advancements. My question is has the FDA taken this into account when developing its guidance? How will FDA address reprocessing protocols if a device is changed due to technical advancements? Would the reprocessor have to start the submission process over?

Reprocessors need to comply with the same filing requirements for modifications to their devices as original equipment manufacturers (OEMs). Any modification to a 510(k) product requires a new 510(k) only if the change or modification in the device could significantly affect the safety or effectiveness of the device. If the technological change could not significantly affect the safety or effectiveness of the device, the reprocessor would not need to file a new 510(k).

Questions Submitted by Senator Hutchinson:

1. **The FDA has recently proposed requiring premarket approval for reprocessed devices. In a July 15, 1998 letter written by Dr. Burlington, he stated FDA's position that "reprocessors' and OEMs' compliance with GMP requirements provides an appropriate measure of public health protection for patients and health care providers by ensuring sufficient control over the individual firm's manufacturing and quality assurance operations. These requirements provide a reasonable assurance that the firm is providing devices that meet appropriate specifications for safety and performance." Dr. Burlingon further noted that FDA had noted a general lack of evidence of adverse patient outcomes attributed to the reuse of single-use devices.**

   Would you explain the policy rationale for the FDA's apparent change in its regulatory approach toward reprocessed devices?

The Agency does not have any additional evidence today of adverse patient outcomes attributed to the reuse of SUDs than it did when Dr. Burlington wrote the July 15, 1998, letter. The rationale behind FDA's decision to reconsider its reuse policy is based on concerns that various stakeholders have raised, including discussion at a series of meetings that focused on the practice of reuse and reprocessing of SUDs, and through FDA's own research efforts. These meetings included the joint FDA-Association for the Advancement of Medical Instrumentation meeting held on May 5-6, 1999; FDA's November 10, 1999, teleconference; and FDA's December 14, 1999, open public meeting. Through these meetings FDA recognized that to continue to exercise enforcement discretion towards SUD reprocessors was inconsistent with its position to regulate all manufacturers in the same manner. In addition, the Agency learned that a growing variety of SUDs are being reprocessed and that reprocessing techniques can vary significantly from one establishment to another.

From FDA's own research efforts in the last two years, we have learned about the difficulty of cleaning and re-sterilizing used medical devices, the variability in the cleaning processes, and the potential effect of reprocessing and re-sterilization on certain devices. Our research suggests that some facilities now performing reprocessing may not even be aware of potential problems with reused SUDs. This information resulted in FDA's decision to develop a reuse regulatory policy based on good science and to regulate third-party reprocessors and hospitals that reprocess in the same manner as it regulates OEMs.

2. **You also state in your testimony that from August 1996 to December 1999, 464 reports were revealed out of 300,000 reports of adverse events that could be related to reprocessed devices.**

How does this compare with the number of adverse events reported from 1993 to 1996, and of the 464 reports that could be related to reprocessed devices, were you able to discern if any were directly a result of a reprocessed device?

From January 1, 1993 - July 31, 1996, FDA received approximately 383,000 reports of adverse events from manufacturers, importers, user facilities, and the general public. FDA has archived the data for all manufacturing reports received prior to August 1, 1996, and does not have the software tools available to identify reports associated with reuse.

Of the 464 reports that FDA received between 1996 to 1999 in which reuse of a SUD likely resulted in an adverse patient outcome, the Agency is unable to directly link the cause of the reported problem to reprocessing procedures.

3. The GAO report states that FDA has acknowledged the difficulty the agency will have in finding appropriate resources to support this expansion of FDA's regulatory authority. GAO also states that FDA has requested the assistance of HCFA and JCAHO to assist in the oversight of hospitals.

Has FDA received a formal response from either party and how will this impact FDA's ability to meet its current responsibilities to review and approve new devices?

Since the July 27, 2000, Senate hearing on reuse FDA has finalized its reuse policy ("Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals"). We anticipate publishing the final reuse policy as a guidance document for industry and FDA staff very soon.

The Health Care Financing Administration (HCFA) has reviewed and concurred with this guidance. We have had several meetings with HCFA to discuss the reuse issue; until we finalized our reuse policy, however, it was difficult to identify tangible ways that HCFA could assist us in this project. With the finalization of our reuse policy, we plan to have a series of meetings with HCFA to identify ways HCFA may use their authorities to ensure that hospital reprocessors are compliant with FDA's regulatory requirements.

FDA has entered into a contract agreement with the Joint Commission on Accreditation Healthcare Organization (JCAHO or the Joint Commission) to provide a written report assessing the practice of reprocessing in U.S. hospitals. The Joint Commission expects to complete this report in early 2001. In addition, on July 11, 2000, FDA representatives met with representatives from the Joint Commission to discuss how JCAHO would assist the Agency in working with hospitals that continue to reprocess SUDs to ensure the safety of used devices and their compliance with FDA regulations. Additional meetings, including one with the Joint Commission's Board of Directors, are planned for this fall to discuss JCAHO's role as auditors of compliance with FDA rules, partners on educational efforts for hospital reprocessors, and trainers of JCAHO surveyors on how to audit hospital reprocessors.

FDA remains optimistic that partnering efforts with HCFA and the Joint Commission are feasible.

4. You stated in your testimony that FDA has not been enforcing the controls it has in place to monitor the repairing, or refurbishing of reprocessed devices.

Why is FDA proposing to expand its regulatory authority instead of fully enforcing its existing regulations?

FDA is not expanding its regulatory authority. Rather, the Agency intends to actively exercise its existing regulatory authority with respect to third-party and hospital reprocessors. FDA will continue efforts collaborating with stakeholders to address issues related to repair and refurbishing of SUDs.

Thank you for making this a part of the public record. If you have further questions, please let us know. Similar letters have been sent to Senators Frist and Hutchison.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

cc: The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education,
Labor, and Pensions

Sec. 300.400 Contamination of Devices Labeled as Sterile (CPG 7124.01)

BACKGROUND:

Certain devices labeled as sterile are frequently used on debilitated patients whose resistance to microorganisms is lower than that of a normal healthy person.

Recent experience has demonstrated that devices labeled as sterile and intended for use under sterile conditions may be nonsterile.

POLICY:

A device labeled as sterile which fails to pass USP tests for sterility is adulterated under Section 501(c) in that its purity and quality falls below that which it is represented to possess and is misbranded under 502(a) in that the label statement "sterile" is false or misleading as applied to a product which is not sterile, but is contaminated with viable organisms.

Device nonsterility should be treated as top priority, because of the seriousness of the health hazard posed by the microbial contamination of sterile products. The responsible firm should be notified of our finding to afford it the opportunity to voluntarily recall its device.

Appropriate legal action and/or recall should be recommended when the examination of a sterile device reveals defective packaging (separated seams, torn or punctured outer wrap) and there is no other protection of package contents. Confirmation of nonsterility by sterility testing is unnecessary in these cases. Inspection reports, exhibits and the results of analysis for defective packaging should be included in the district recommendation to *HFZ-300*. The results of analysis should include the number of units examined, the number of units found defective, the types of defects identified and the range in size and numbers of holes or broken seams found per unit.

In situations where there is more than one wrap or there are questions regarding whether the nature of the packaging defect meets the conditions outlined in this guideline, the district should consult with *HFZ-300*.

Material between asterisks is new or revised

Issued: 8/23/74
Reissued: 6/11/76
Revised: 10/1/80, 9/24/87, 3/95

Sec. 300.500 Reuse of Medical Disposable Devices (CPG 7124.16)

BACKGROUND:

Investigations by the Food and Drug Administration (FDA) and other Federal agencies have disclosed that a number of health care institutions have engaged in the practice of reusing single use sterile disposable medical devices. Such devices may not be amenable to resterilization and/or reuse. The FDA is not aware of any data which would establish conditions for the safe and effective cleaning and subsequent resterilization and/or reuse of any disposable medical devices.

In January of 1975, the Bureau of Health Insurance of the Social Security Administration issued State Agency Letter No. 29 concerning the Reuse of Disposable Guidewires and Catheters. The letter stated that such devices were not to be reused. Since that time, the FDA has received a number of inquiries relative to the economics of its policy as related to issues concerning protection of the public health, and has been requested to reconsider and reevaluate the position it has taken.

The FDA, in recognition of the validity of the concerns expressed by all parties involved in this matter has reviewed its position on this issue, but finds that there is a lack of data to support the general reuse of disposable medical devices, including disposable guidewires and catheters. The fact that devices are labeled disposable is indicative of this lack of data. In order for a device to be considered "reusable", it must be capable of withstanding necessary cleaning, and resterilization techniques and methods, and continue to be safe and reliable for its intended use.

The FDA has concluded, therefore, that the institution or practitioner who reuses a disposable medical device should be able to demonstrate: (1) that the device can be adequately cleaned and sterilized, (2) that the physical characteristics or quality of the device will not be adversely affected, and (3) that the device remains safe and effective

for its intended use. Moreover, since disposable devices are not intended by the manufacturer or distributor for reuse, any institution or practitioner who resterilizes and/or reuses a disposable medical device must bear full responsibility for its safety and effectiveness.

POLICY:

The reuse of disposable devices represents a practice which could affect both the safety and effectiveness of the device. Information developed regarding this practice should be referred to the *Center for Devices and Radiological Health* for review and evaluation.

Material between asterisks is new or revised.

Issued: 11/11/77
Reissued: 10/1/80, 7/1/81
Revised: 9/24/87

Sec. 300.600 Commercial Distribution with regard to Premarket Notification (Section 510(k)) (CPG 7124.19)

BACKGROUND:

Many questions have been raised concerning what constitutes commercial distribution. This Compliance Policy Guide is based on a March 24, 1978, response to a formal request for an Advisory Opinion on this subject (Docket Number 77A-0307).

POLICY:

If a manufacturer can meet all of the following conditions, we consider a device to presently be in commercial distribution and also to have been in commercial distribution before May 28, 1976, even though no units of the device had been delivered to purchasers or consignees before that date:

1. The device was displayed, advertised, or otherwise offered for sale before May 28, 1976, for a specific intended purpose or purposes, with no limitations (e.g., no limitation to research or investigational use);

2. The manufacturer had, before May 28, 1976, accepted, or been prepared to accept, at least one order to purchase the device that resulted, or would have resulted, in a contract of sale for the device in the United States, generally with delivery to occur immediately or at a promised future date;

3. The device was not being offered or accepted only for research or investigational use; *and*

4. The manufacturer of the device can provide adequate documentation establishing (1) through (3) above to the satisfaction of the Food and Drug Administration.

This opinion affects device firms' promotional activities during the pendency of 510(k)'s (premarket notification submission). Although a firm may advertise or display a device that is the subject of a pending 510(k) -- in the hope that FDA will conclude that the device is substantially equivalent to a pre-amendments device -- a firm may not take orders, or be prepared to take orders, that might result in contracts of sale for the device unless limited to research or investigational use.

Material between asterisks is new or revised

Issued: 7/28/78
Reissued: 10/1/80, 9/24/87

Sec. 300.700 Direct Reference Authority for Class III Medical Devices Without a Premarket Notification (510(k)) or an Approved Premarket Approval Application (PMA) (CPG 7124.30)

BACKGROUND:

The Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act (the Act) established three regulatory classes for medical devices based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The Act, as amended, defines a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury.

Class III medical devices are required to have an approved premarket approval application (PMA).

Additional questions for the record to Dr. Jan Heinrich, GAO,
Committee on Health, Education, Labor, and Pensions,
June 27th hearing, "Reprocessing of Single-Use Medical Devices."

Chairman Jeffords

1. What is the cost-saving benefit to hospitals from reprocessing of single-use devices? Are savings attributable to the low cost of reprocessing, or the competition driving down the price of new devices?

Dr. Heinrich: We were able to document that reprocessed single-use devices are much less expensive than new devices. Third-party reprocessing firms provide a reprocessed device for one-half of the price of a new device, and we found three hospitals that were able to reprocess some types of cardiac catheters for less than 10 percent of the price of a new device. However, we were unable to determine the extent to which the competition from reprocessing has lowered the cost of new devices. On the one hand, many of the physicians and hospital executives we contacted certainly believe that it has generally lowered the prices of new devices. For example, a majority of the gastroenterologists we contacted told us that the prices they paid for new single-use GI biopsy forceps had decreased, even though none of their facilities reprocessed these devices. Conversely, device manufacturers told us that the prices of their devices had declined for other reasons, such as the growth of purchasing cooperatives.

2. In the hospital setting, infections are, unfortunately, commonplace. When a patient gets an infection from surgery using reprocessed devices, how can we be sure that the infection was not attributable to a reprocessed device?

Dr. Heinrich: We can not be sure that an individual infection was not caused by a reprocessed device, or, for that matter, by any piece of surgical equipment or any particular surgical procedure. Surveillance systems for hospital infections can identify, and trace the cause of, clusters of infections that presumably have a common cause. For example, hospital infection control personnel recently traced an outbreak of infections in a hospital neonatal intensive care service to bacteria growing under the fingernails of some nurses. But, because the baseline rate of infections is so high and because there are so many possible sources of infection in hospitals, it is very difficult to determine the cause of a single infection.

3. How are devices labeled when hospitals receive them from third-party reprocessors? Are they labeled the same as new devices? If not, does this violate FDC Act requirements on mislabeled products?

Dr. Heinrich: The third-party reprocessors we contacted provide labels that identified the device, the reprocessor, and the client hospital, and list the number of times that the device has been reprocessed. The labels do not include any instructions for use. The devices are returned to facilities that already have instructions from the manufacturer's

original labeling of the device. FDA has not challenged these labels, but we did not independently investigate their statutory propriety.

Senator Hutchinson

1. Later testimony from the Association of Disposable Device Manufacturers cites a study in which 75 percent of 1,200 reprocessed devices on a hospital shelf were found unsuitable for use. Did GAO come across any of these studies and what was your analysis of them?

Dr. Heinrich: In our work, we came across many reports of allegedly unclean or nonsterile reprocessed single-use devices. While it is difficult to verify the validity of many of these allegations because of the variety of existing sterilization methods and the lack of standards for many devices, some of them do raise concerns about the effectiveness of reprocessing procedures. For example, we noted in our report that FDA has changed its sterility testing procedures for GI biopsy forceps because of evidence that some reprocessed forceps may not have been sterile. Furthermore, we found evidence that reprocessing is not always done correctly, even for devices approved for multiple use. For that reason, even though there is substantial evidence that selected devices can be safely reprocessed, we believe that increased FDA oversight of single-use device reprocessing is warranted.

2. Would you elaborate on the GAO's findings with respect to healthcare professionals questioning the single-use label and efforts by manufacturers to bypass this label?

Dr. Heinrich: Many healthcare professionals told us that they question the validity of the single-use label for many devices. Some of them believe that device manufacturers have changed the labels of some devices from reusable to single-use only without altering the devices themselves. As we discussed in our report, some healthcare professionals believe that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable. FDA's approval requirements for reusable devices are more extensive than those for single-use devices, providing another incentive for manufacturers to market devices as single-use. In addition, FDA can not require manufacturers to prove that single-use devices really can not be used more than once. Finally, some healthcare professionals point out that some single-use devices are routinely reprocessed and used again without apparent ill effects. For example, electrophysiology catheters, devices inserted into the heart to measure cardiac functioning, have been widely reused for twenty years, even though every catheter approved by FDA has been approved for single-use only.

We were not able to demonstrate that manufacturers intentionally sought to bypass the single-use label. However, in some instances manufacturers did contribute to the skepticism about the labeling of some devices as single use. For example, a major manufacturer of pulse oximetry sensors (devices that measure blood oxygen levels) offers to "recycle" the sensors, selling remanufactured sensors at reduced prices. On the face of it, this practice appears to be close to the reprocessing of oximetry sensors done by third-party reprocessing companies. Similarly, we found that manufacturers of some single-use devices had sent letters with sterilization instructions to healthcare institutions. Some of the institutions used these instructions in their reprocessing programs.

3. What are the most commonly reprocessed devices?

Dr. Heinrich: We can not answer your question directly because there is no reliable data about the actual extent of reprocessing for particular devices. We included as an appendix in our report a FDA-provided list of frequently reprocessed single-use devices. These include cardiac catheters, biopsy needles and forceps, endoscopic instruments, and surgical blades.

Question for the Record from Senator Frist

Q: "Reprocessing has been in practice for the last 20 years, and according to the GAO Report presented today, with "Little Evidence of Harm." When this Committee considered FDA Reform during the 105th Congress, this issue was not raised. Why, after years of practice, has reprocessing became [sic] such a critical issue in the last three years?"

While some form of reprocessing has existed since the 1980s, reprocessing has changed dramatically over the past two decades due to the development of increasingly complex medical devices. In addition, patients have only recently begun to be aware that single use devices are being reused. (See attached 1999 articles from Forbes Magazine and U.S. News and World Report.) These two developments catalyzed numerous laboratory studies of the safety of reprocessed single use devices. The data from most of those studies, some of which were conducted by FDA scientists, was reported in 1999 and revealed serious safety risks associated with reprocessing.

Introduction of More Complex Devices

Innovative devices such as delicate percutaneous transluminal coronary angioplasty (PTCA) balloon catheters were developed within the past twenty years. The unique features and components of these products, many of which are obvious to the naked eye, raise serious concerns for reprocessing. When, despite these features, such devices began to be reused, reprocessing in general came under greater scrutiny. That scrutiny revealed that even devices such as electrophysiology catheters which had been reprocessed for 20 years were not safe to reuse in patients. (See attached abstract from FDA's Office of Science and Technology.)

In addition, the advent of the reprocessing industry has further altered the character of reprocessing. Greater numbers of patients are being exposed to reprocessed single use devices, and the types of devices being reprocessed are even more complex – many classified as "high risk" by FDA. Through various marketing strategies employed by reprocessors, cost conscious hospitals have been led to conclude that, while the hospital itself is incapable of cleaning a certain type of device, the third-party reprocessor can safely reprocess it while saving healthcare dollars. These marketing techniques typically include statements regarding "FDA approval" or "FDA inspection," falsely implying that the FDA has found reprocessing of the particular device to be safe and effective. In fact, FDA has not found that any single use devices can be safely reprocessed. Each of the three reprocessed disposable device types studied by FDA's Office of Science and Technology (PTCA catheters, electrophysiology catheters and biopsy forceps) have been deemed "high risk" by FDA due to risks associated with inadequate cleaning, sterilization or functionality post-reprocessing.

Patient Awareness

At the June 27th hearing we heard about a patient who entered a Florida hospital for a routine kidney stone removal procedure. The procedure, however, was complicated by use of a reprocessed stone retrieval device – the metal of which had been so fatigued that the basket portion broke off from the remainder of the device and remained lodged within the patient. The attending physician performed emergency surgery to remove the failed device and reattach the severed ureter and bladder. The patient has since had to undergo a second surgery due to complications involved in the device removal.

Unlike most Americans, the daughter of this Florida patient, Georgia Abernathy, through her work for a medical device manufacturer, was aware of the practice of reprocessing and its threat to patients. For more than two weeks Ms. Abernathy and her cousin, a urologist, investigated and questioned hospital personnel about the reuse of urological stone retrieval devices before they were told that the device used on Ms. Abernathy's mother had been reprocessed. The family's tenacity and familiarity with the

risks of reprocessing single use devices equipped them with the knowledge to investigate a practice of which most U.S. citizens are unaware.

This incident reveals not only that the risks involved with reprocessing are mounting, but also that the supposed cost savings attributed to reprocessing may not be real. Does the Florida hospital that used this reprocessed stone retrieval basket calculate the additional thousands of dollars in surgical costs to the cost of reprocessing? No, in fact this hospital is probably very similar to those interviewed by the GAO who report a 50% cost savings from reprocessing. If adverse events were tracked and appropriately attributed to reprocessing, we might find that reprocessing results in no cost savings at all, and, in fact, increases healthcare costs.

Most reprocessing injuries like this are neither investigated nor reported. The fact that a reprocessed single use device was used on the patient is not even noted in the patient's records. It is not surprising, therefore, that there is little available clinical evidence of patient harm. This lack of availability should not be confused with a lack of patient risk. There is a growing body of laboratory data, much of it developed by the FDA and independent laboratories, showing that reprocessed devices are not sterile and do not function properly. U.S. patients are at serious risk of both infection and functional failure caused by reprocessed single use devices.

Abstracts for the 2000 FDA science forum from [illegible] OST [illegible].

Effects of Use and Reprocessing on Single Use Coronary Catheters. S. A. Brown[1], K. Merritt[2], V. M. Hitchins[2], and T. O. Woods[1]. [1]*Division of Mechanics and Materials Science and* [2]*Division of Life Sciences, CDRH/ FDA, Rockville Md-20852.*
Although sold for single use only, some medical devices, such as coronary catheters, are being reprocessed for reuse. Over 400 PTCA and 300 EP catheters have been retrieved after single patient use at Walter Reed Army Hospital. After disinfection and cleaning, a variety of performance characteristics were determined, and then some were subjected to ETO sterilization and simulated reuse. The results demonstrated that cleaning was not a trivial problem. The balloon compliance data demonstrated model specific changes. Some catheters became more sticky making insertion more difficult. Some models of EP's were non-lumen, whereas others had hollow cores sometimes contaminated with blood. Damage to electrode seats exposed the lumens as well as copper wires connected to the electrodes. Unbeknownst to the user, subtle changes in device appearance may be associated with major changes in the performance of a used or reused device.

The Effect of Reprocessing on Single Use Electrophysiology Catheters T.O. Woods[1], S.A. Brown[1], K. Merritt[2], & V.M. Hitchins[2]. [1]*Division of Mechanics & Materials Science,* [2]*Division of Life Sciences, CDRH, FDA, Rockville, MD 20850*
Electrophysiology catheters (EPs) are one of the single use devices that are most often reported to be reprocessed and reused. Once it has been established that a used device can be cleaned and resterilized, it is necessary to show that its mechanical behavior has not been adversely affected. Torque and trackability, two clinically relevant mechanical properties of EPs, will be determined for a solid and hollow configuration of one model of EP catheter. The two types reflect a manufacturing change that was made without a change in model name. The two properties will be determined for new, unused catheters; for catheters after use in a single patient; and for used catheters subjected to a number of cycles of ethylene oxide sterilization, simulated reuse and reprocessing cycles. Results for the two catheter types will be compared.

1. **Dr. Frist: Dr. Clough, when seeking reimbursement from the Health Care Financing Administration [HCFA] do providers indicate whether or not a reprocessed device was used, and are the cost savings from the reprocessing passed on to the taxpayers?**

Response: When we are dealing with reprocessing a high cost item that lends itself to large cost savings, we at the Cleveland Clinic feel that it is only fair to share that cost savings with the patient or payer. I cannot speak for other hospitals, but we have a process for identifying a reused device and allocating its cost over the number of times it is reused. As an example, below is a description of our internal process as it relates to electrophysiology catheters.

CLEVELAND CLINIC FOUNDATION

BILLING PRACTICE FOR

REPROCESSED ELECTROPHYSIOLOGY CATHETERS

An electrophysiology examination or an ablation procedure are inpatient procedures which involve complex electrical mapping of the heart and corrections of the heart's electrical process. Routine procedures typically use three catheters, and complex procedures may use from four to six catheters. About a third of the procedures are complex.

The most common catheters and their price to CCF are listed below.

Bard Steerable Catheter.....	$475
Webster Steerable Catheter.....	$600
Mansfield Explorer.....	$235
EPT Steerocath "T".....	$745
EPT Blazer II "T".....	$745
EPT Octapolar.....	$800
Duo-Decapolar.....	$995
USCI Quad Catheter.....	$245

To establish our charge for the device, a mark-up schedule has been developed. It is as follows:

For devices which cost between $0 and $35, the mark-up is 100%
For devices which cost between $36 and $150, the mark-up is 75%
For devices which cost between $151 and $999, the mark-up is 65%
For devices which cost over $1,000, the mark-up is 50%.

Thus, the charge for a EPT Octapolar would be $800 x 0.65 plus $800, which equals $1320.

If this device is scheduled to be reprocessed and reused five times, the charge to the payer would be $1320, plus $40 for reprocessing, divided by 5, which equals $272.

The process described above is the method by which CCF computes its charge to all payers, independent of the payer's particular form of payment. If the payer is discounted fee-for-service, the benefit to the payer is in the reduced charge due to reprocessing. If the payer is on a fixed payment scheme, such as Medicare, the payer obtains the benefit of the hospital's reduced cost in subsequent years when the fixed payments are updated, based on the hospital's charge data as reflected in the Medicare cost reports.

2. **Dr. Frist: What percentage of devices reprocessed by hospitals are the result of devices which are opened for surgery but not used in patients but simply repackaged and sterilized for reuse?**

Response: At the Cleveland Clinic, 30-40% of "single-use devices" sent to third-party reprocessors are surgical equipment opened but not used. We do not reprocess this equipment in-house.

AMDR
Association of Medical Device Reprocessors

July 19, 2000

AMDR's Responses to Follow-Up Questions Posed by Senators Jeffords and Frist

Questions submitted by Chairman Jeffords for Vern Feltner, AMDR

1. *How are devices labeled when hospitals receive them from third-party reprocessors? Are they labeled the same as new devices? If not, does this violate FDC Act requirements?*

AMDR Response: AMDR reprocessors generally include the following information on their product labels: reprocessor's name and address; original manufacturer's name; hospital's name; prescription legend; a notation that the product is sterile; sterilization date; and the reprocessor's tracking information (e.g., bar code, work order number, etc.). To the best of AMDR's knowledge, the label information provided by AMDR reprocessors satisfies FDA requirements.

Questions submitted by Senator Frist for Vern Feltner, AMDR

1. *What are the current requirements to be a reprocessor?*

AMDR Response: FDA currently enforces the following requirements with respect to third-party reprocessors: Registration and Listing (FDC Act § 510; 21 C.F.R. Part 807); Medical Device Reporting (FDC Act § 519(a); 21 C.F.R. Part 803); Medical Device Tracking (FDC Act § 519(e); 21 C.F.R. Part 821); Medical Device Corrections and Removals (FDC Act § 520(f); 21 C.F.R. Part 806); Quality System Regulation (FDC Act § 520(f); 21 C.F.R. Part 820); and Labeling (FDC Act § 502; 21 C.F.R. Part 801). See "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals"; Draft Guidance (Feb. 8, 2000) at 5.

2. *What medical certification is required? Who do you register with?*

AMDR Response: Third-party reprocessors are not required to obtain medical certification. Third-party reprocessors must register with FDA, pursuant to 21 C.F.R. Part 807.

3. *How are your packaging and instructions for use insert different than those of the original manufacturer, and who determines what that insert states?*

AMDR Response: The hospitals that AMDR companies serve retain ownership of their devices throughout the reprocessing process. Since the hospitals receive instructions for use when they originally purchase a device, AMDR members do not send them another copy.

4. *If a reprocessor has a device returned to them, from a health care provider, due to failure or lack of sterility, must they file a MedWatch Report on each of those device failures?*

AMDR Response: Yes. Pursuant to FDA's Medical Device Reporting requirements, third-party reprocessors must file MedWatch Reports with FDA under the following circumstances: If the reprocessor "receives information or otherwise becomes aware of information, from any source, that reasonably suggests" that a device reprocessed by the reprocessor "[m]ay have caused or contributed to a death or serious injury" or "[h]as malfunctioned and such device or similar device [reprocessed by the reprocessor] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." See 21 C.F.R. § 803.50(a).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administrati
Rockville MD 20857

JUL 20 2000

The Honorable James M. Jeffords
Chairman
Committee on Health, Education, Labor,
and Pensions
United States Senate
Washington, D.C. 20510-6300

Dear Mr. Chairman:

This is in response to a request by Senator William H. Frist to David W. Feigal, Jr., M.D., M.P.H., Food and Drug Administration (FDA) witness at the June 27, 2000, hearing before the Committee on Health, Education, Labor, and Pensions on the reuse of medical devices labeled for single use. Specifically, Senator Frist inquired whether data underlying an abstract, "The Effects of Use and Simulated Reuse on PTCA Balloons and Catheters" by Brown, et al., had been made public. Dr. Feigal responded affirmatively and offered to provide the Committee other publications and meetings where similar data have been presented. Enclosed are six abstracts and presentations by FDA staff presenting research results on the reuse of single use medical devices.

If we can be of further assistance, please contact us.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

cc: The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Health, Education, Labor,
and Pensions
United States Senate
Washington, D.C. 20510-6300

cc: The Honorable William H. Frist
United States Senate
Washington, D.C. 20510-4205

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- Abstract and Presentation by CDRH/OST Investigators Katharine Merritt, Vicki Hitchins, Terry Woods, Stanley Brown at AAMI/FDA Conference "The Reuse of Single-Use Devices: Practice, Patient Safety and Regulation" May 5-6, 1999 at Hyatt Regency Crystal City Hotel

- Article for 24th Annual Meeting of the Society for Biomaterials April 22-26, 1998, San Diego, California 'Cleaning Biological Debris from Materials and Effects of the Cleaning Process on Material Properties" by K. Merritt, V. Hitchins, S. Brown, T. Wood, FDA/CDRH/OST/DLS&DMMS.

- Abstract from FDA 2000 Science Forum from OST

- Poster Presentation at Biofilms 2000 July 19 Big Sky Montana "Biologically Relevant Test Soils and Method to Detect Residual Soil for Validation of Cleaning Medical Devices" by K. Merritt, V. Hitchins, M. Willison FDA/CDRH/OST/DLS

- Abstract for 2000 Society for Biomaterials "The Effects of Use and Simulated Reuse on PTCA Balloons and Catheters" by S. Brown, K. Merritt, T. Woods, V. Hitchins FDA/CDRH/OST

- Reprint "Safety and Cleaning of Medical Materials and Devices" by Katharine Merritt, Victoria Hitchins, Stanley Brown FDA/CDRH/OST/DLS

ABSTRACTS AND PRESENTATIONS

BY CDRH/OST INVESTIGATORS

STUDYING REUSE OF SINGLE USE DEVICES

~~JANUARY~~ June 2000

AAMI/FDA Conference

The Reuse of Single-Use Devices: Practice, Patient Safety and Regulation

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RE-USE OF DEVICES: *CLEANING ISSUES*
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FDA/CDRH/OST

Special Thanks
Walter Reed Army Hospital (interventional cardiology)
NIH, Materials Services

Any device to be reused must be cleaned

1. Cleaning method
   A. CDRH Safety Rules
      must be disinfected before handling
   B. Develop a method to clean after disinfection
      used a 96 well polysytrene plate format, not amenable to scrubbing
      The object was to get data on cleaning efficacy available as optical density and thus quantitative data for analysis
      used bacteria, blood, and protein
      i. most disinfectants "fix" the protein and bacteria to the material and prevent adequate cleaning
      ii. NaOCl based bleach did not hinder further cleaning
      iii. Detergents and surfactants do not clean protein and bacterial adequately
      iv. Detergents with enzymes are effective
      v. The less the material is allowed to dry prior to disinfecting and cleaning, the better the cleaning

2. PTCA balloon catheters were the device studied
   complex, delicate materials and design, many inner channels and interstices not amenable to scrubbing, expensive, known to be a target for re-use
   Arranged with Walter Reed Army Hospital, Interventional Cardiology, to acquire PTCA balloon catheters after single use. Placed in a bag with water, then in a bucket, and we picked up weekly
   We received many designs from several manufacturers. We learned how to clean the different types.
   This is a talk on cleaning and the materials and balloon compliance issues will be presented in the next talk (Stanley Brown).

The standard procedure was to pour bleach into each bag with the catheters to make approximately 10%, or if there was no water, pour in 10% bleach. These were left for one hour. The bag was agitated or rolled over once or twice in the hour. Then the wire guide lumen was flushed using a syringe with 10% bleach into the bleach in the bag and left for 30 minutes. If the guide wire was still in the lumen, it had to be removed before the syringe could be attached for flushing. The guide wire is long and unwieldy and was difficult to remove without splashing. It was safer to cut the wire at the manifold and then push it in a little. This could be done under bleach solution. The problem with this procedure is that there is a cut end of the guide wire that is being pulled through the balloon later after bleach disinfection. This could cause damage to the lumen.

The outside was thus subjected to bleach for one and a half hours. Then the device was placed into water with detergent with enzyme. Attempts were made to visualize any problems before removing the catheter from the bag of bleach. These included making sure all parts had been exposed to bleach and whether there was blood in the balloon or the balloon access port. If this was present, then the balloon channel was flushed with bleach and left for 30 minutes.

A. Guide wire lumen

These were often full of blood, sometimes it was clotted and the lumen not patent. Instillation of bleach by leaving the syringe attached and slowly introducing the bleach, sometimes over an hour, usually opened the lumen. Occasionally a guide wire was used to disrupt the clot. This was all done under a bleach "blanket".

However the devices with side rail ports (monorail) could not be disinfected this way. It was necessary to remove the catheter tip from the bag and with the aid of a magnifying lens insert a 26 gauge

needle with a syringe of bleach into the distal end of the catheter and expel bleach with the hope that the blood came out an access port that was still in the bag or in a towel of bleach.

The devices with a Tougy often had blood on the threads. These needed to be exposed to the bleach and then tightened correctly so that the channel could be flushed also.

B. The Balloon Channel

This is a closed channel and therefore has to be flushed extensively by repeatedly inserting and withdrawing water. These were flushed repeatedly with water to remove the contrast dye. The estimated pressure used with a finger on the 3 cc syringe was 3-4 atm. Failure to adequately remove the dye will lead to the dye drying and forming crystals and a plugged balloon or balloon channel. This could take an hour or several days. A plugged balloon is usually obvious, but a plugged channel will usually not be apparent until the balloon is put into use: which could be the next patient.

Blood in the balloon means that there is a leak in the channel or in the balloon. At first we noted these and discarded them. Then we decided we wanted to save them and determine the source of failure. These channels were flushed with bleach and left for about 30 min for disinfection. These were the only balloons that got subjected to bleach on the both the external surfaces as well as the internal balloon and balloon channel.

There is sometimes blood in the balloon manifold port. This is very difficult to remove since flushing just pushes it into the balloon channel. Sometimes careful insertion of a small amount of bleach with immediate withdrawal repeatedly will clear it. However this could be driven into the balloon port and not recognized as being there.

C. PTCA is a device with many models. They do not all behave the same.

some devices and balloons clean easily, some seem to be always plugged.

some wire guide lumens kink easily, get clogged, or leak

Results of compliance testing of the balloons will be presented in the next talk

D. Simulated re-use

In order to study the effects of multiple use of the PTCA, a simulated re-use protocol was developed. Defibrinated sheep blood was placed into a polyethylene bag and then a sterilized PTCA was gently coiled and placed in the bag with the manifold exposed and elevated. A syringe was filled with blood, attached to the wire guide lumen which was then filled with blood. An inflator was filled with water and attached to the balloon manifold and the balloon was inflated to 6 atm. The bag was agitated and the syringe was used to flush fresh blood in each 30 min. The set-up was left for 2 hours. The PTCA was then cleaned as described above, dried, packaged, and ethylene oxide gas sterilized. (NIH kindly did this for us on a special weekend research run). The balloons were tested as will be described in the next talk. Then a second simulated re-use was undertaken.

E. Re-sterilization

Some PTCA's with Tougy's were deliberately contaminated with organisms and protein and then subjected to ETO sterilization. NIH materials services kindly agreed to do the ETO for us using their standard protocol but in a separate over the weekend research run.

The wire guide lumen was filled with S. epi in TSB broth and left overnight at 37C. The wire guide lumen was then flushed with a saturated solution of fibrin and left for the day at room temperature. This was then flushed out and the device left overnight. The next day a suspension of bacillus spores (B. st and B. subtilis niger) was added to the lumen and left until the next day. This was then flushed out, sometimes left to dry, and then packaged for sterilization. The sterilized device was then aseptically cut into segments and cultured in TSB. About half of the catheters grew organisms in the middle segments. The main organism grown was the S. epi. Only one catheter that had received two treatments with S. epi and the spores and then not carefully dried had bacilli (both of the species) as well as the S. epi surviving.

Other Associated Devices

Inflators: these often had blood on them, but they cleaned well in the bleach, detergent regimen. The dye was flushed repeatedly and only once did we get a plug of dye in the tubing. The gauge sometimes filled with liquid and rusted, but still worked.

Since we were retrieving PCTA's, Walter Reed offered us the EP's and Ablators

These were usually contaminated with blood and were cleaned with the same protocol with bleach in the bag, detergent, and water. The EP's cleaned easily. The ablators are not sealed devices and dripped cleaning solution when hung to dry. The function of these devices has not been tested.

SPECIAL ISSUES

Considerations

Safety for the person doing the cleaning

Safety for the next patient

debris, device failure, change in device performance, e.g. balloon tolerances and profiles

Unknown materials and processing aids lost or added

coatings, lubricants, sterilization residues

Sterility issues

bioburden has changed

devices must be dry before gas sterilization

not a rapid turnaround

the issue of pyrogenicity must be addressed and special water would be needed for devices to be reused in the clinical setting.

EFFECT OF USE AND SIMULATED REUSE, ON MATERIALS AND PTCA BALLOONS & CATHETERS (Percutaneous Transluminal Coronary Angioplasty)

AFTER SINGLE USE @ WALTER REED ARMY HOSPITAL

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AAMI Conference on *The Reuse of Single Use Devices: Practice, Patient Safety and Regulations.*
Crystal City VA, May 5-6, 1988.

EFFECT OF CLEANING ON MATERIALS

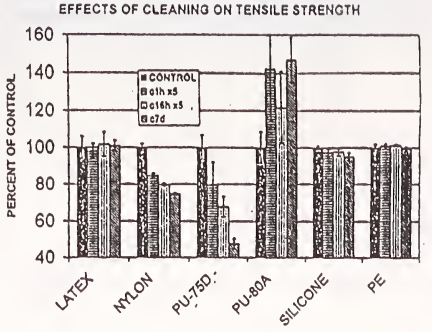
MATERIALS TESTED:
LATEX, NYLON 6/6, POLYETHERURETHANE: PELLETHANE
2363-75D & 2363-80A, SILICONE, POLYETHYLENE

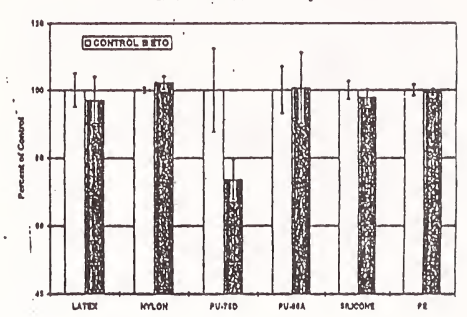
METHODS:
STRIPS CUT INTO ASTM D412 "D" "DOG BONES"
"CONTROL" NO TREATMENT
"c1x5" 1:10 CLOROX for 1 HOUR x5 TIMES
"c16h x5" 1:10 CLOROX for 16 HOURS (OVERNIGHT) x5 TIMES
"c7d" 1:10 CLOROX for, 7-10 DAYS
ALSO TESTED EFFECTS OF ETO STERILIZATION DONE AT NIH CLINIC
TESTED IN TENSION ACCORDING TO ASTM D412 & D638

ANALYSIS OF USED PTCA CATHETERS

USED ONCE @ WALTER REED ARMY HOSPITAL
placed in bag of water & brought to lab
>330 Catheters, 8 major Mfg's, >25 models
"USED" PCTA CATHETER PROTOCOL I
CLEAN (as per Merritt et al); INSPECT FOR DAMAGE (KINKS, ETC.)
COMPLIANCE TESTING PROTOCOL:
INFLATE to 1, 3, 6, 10, 12 Atmospheres (twice)
MEASURE: DIAMETER on "shadow box"
WASH AND DRY BALLOON

"SIMULATED REUSE" PROTOCOL:
INSERT IN SHIPPING TUBE
RESTERILIZE WITH ETO @ NIH
90% hydrochlorofluorocarbons; 10% Ethylene Oxide (75-21-8)
129-132 °F (53.8 - 55.5 °C) ; 50-65% relative Humidity
130 Min followed by 12 hours aeration.
SIMULATED REUSE:
2 HRS IN BLOOD WITH WIRE GUIDE LUMEN FULL
AND BALLOON INFLATED TO 6 ATM WITH WATER
CLOROX CLEAN AS DESCRIBED PREVIOUSLY
COMPLIANCE TEST & DRY BALLOON

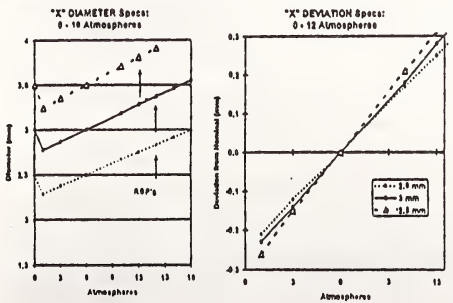




PTCA RESULTS PRESENTED

MANUFACTURERS' COMPLIANCE SPECIFICATIONS
FROM PACKAGE INSERTS
'RBP' = RATED BURST PRESSURE
'ERROR BANDS' = + & - 2%, 5%, or 10% of specs
DIAMETER vs PRESSURE
AS PER PACKAGE INSERT
DEVIATION vs PRESSURE
(= DIAMETER - NOMINAL)

USED BALLOONS: DEVIATIONS
USED & 2x SIMULATED REUSE: DEVIATIONS
USED & 3x ETO STERILIZATION: DEVIATIONS



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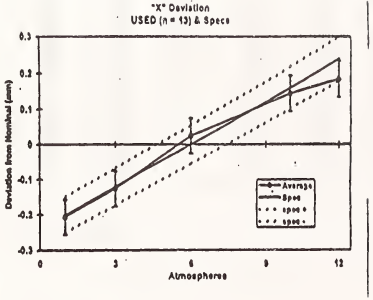
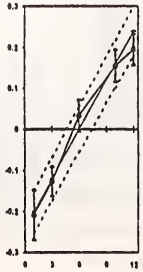
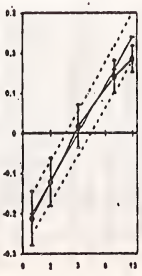


SPECIFICATION + & - 2%

"X" USED



"X" USED, SIM 1x



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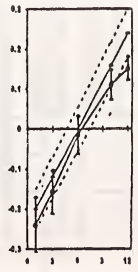
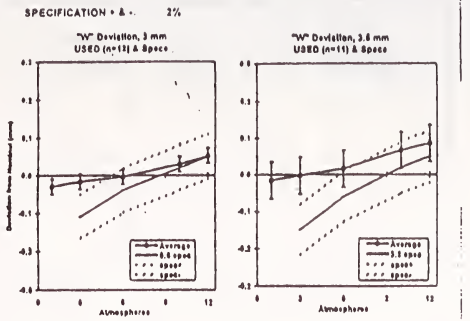
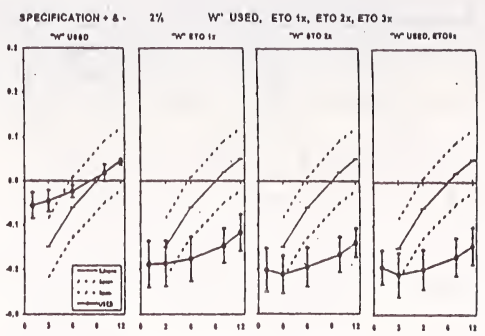
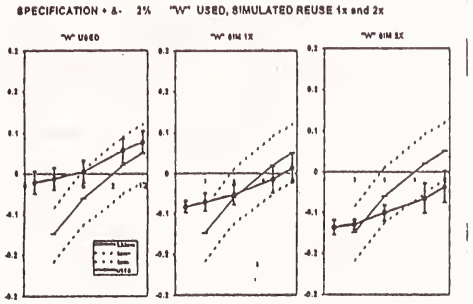
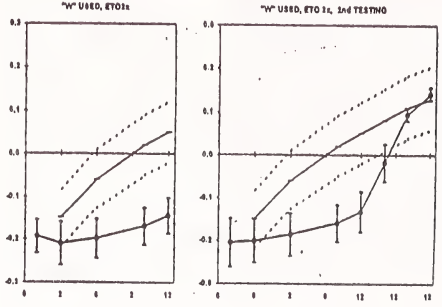
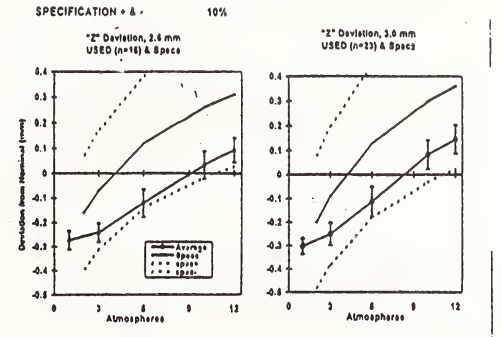


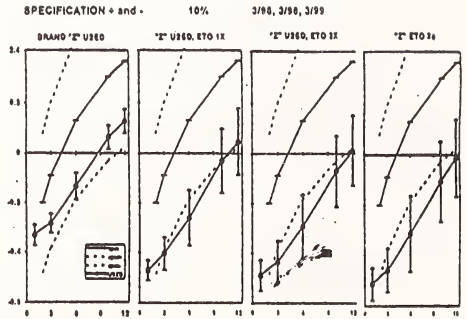

SPECIFICATION + & - 2%
"W" Deviation, 3 mm
USED (n=11) & Specs
"W" Deviation, 3.6 mm
USED (n=11) & Specs
Average
3 specs
Atmospheres

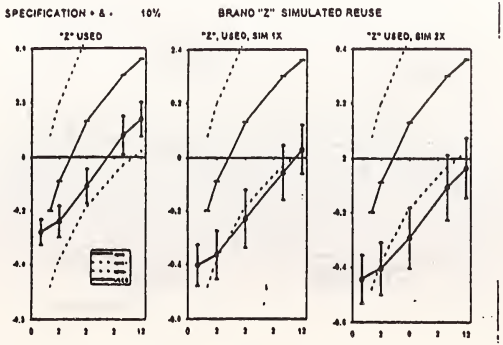

SPECIFICATION + & - 2%
W" USED, ETO 1x, ETO 2x, ETO 3x
"W" USED
"W" ETO 1x
"W" ETO 2x
"W" USED, ETO3x

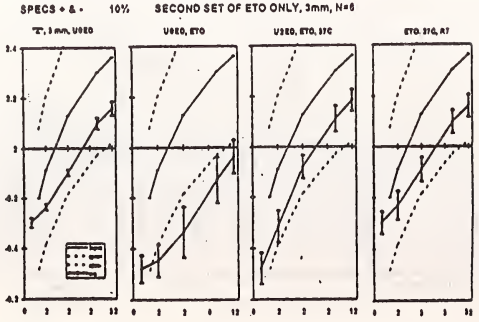

SPECIFICATION + & - 2%
"W" USED, SIMULATED REUSE 1x and 2x
"W" USED
"W" SIM 1X
"W" SIM 2X

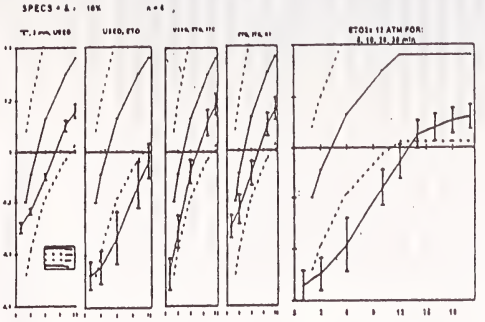

"W" USED, ETO3x
"W" USED, ETO 2x, 2nd TESTING


SPECIFICATION + & - 10%
"Z" Deviation, 2.6 mm
USED (n=16) & 8pacs
"Z" Deviation, 3.0 mm
USED (n=23) & 8pacs
Deviation from Nominal (mm)
Atmospheres
Atmospheres

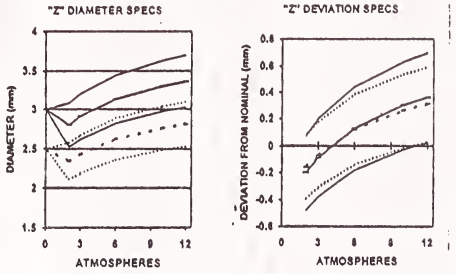

SPECIFICATION + and - 10% 3/98, 3/98, 3/99
BRAND "Z" USED
"Z" USED, ETO 1X
"Z" USED, ETO 2X
"Z" ETO 3x


SPECIFICATION + & - 10% BRAND "Z" SIMULATED REUSE
"Z" USED
"Z", USED, SIM 1X
"Z" USED, SIM 2X


SPECS + & - 10% SECOND SET OF ETO ONLY, 3mm, N=6
"Z", 3 mm, USED
USED, ETO
USED, ETO, 2TC
ETO, 2TC, R7



SPECIFICATIONS SHOWN WITH ERROR BANDS OF + & - 10%



DISCUSSION & CONCLUSIONS

MATERIALS TENSILE TESTING:
EFFECT OF CLEANING SOLUTIONS ON "A MATERIAL CALLED PLASTIC" is MATERIAL SPECIFIC - NOT GENERIC

CATHETER CLEANING PROBLEMS:
FLUSHING ALL THE DYE OUT OF THE BALLOON IS NOT A TRIVIAL PROBLEM.
RADIOOPAQUE DYE CRYSTALLIZES WHEN IT DRIES:

USED PTCA COMPLIANCE TESTING:
NOT ALL DEVICES ARE THE SAME AS SPECIFICATIONS

SOME BALLOONS MAY BE STRETCHED DUE TO OVER INFLATION
as indicated by a WAVY GUIDE WIRE LUMEN

SOME MAY SHRINK WITH REPROCESSING (ETO)

SOME MAY STRETCH OVER TIME AT PRESSURE

MAY BE MATERIAL SPECIFIC

ACKNOWLEDGEMENTS:
Capt Heidi Vigeant R.N. & Major David Gillespie, M.D.
Vascular Surgery Service at WALTER REED & NIH FOR ETO STERILIZING

Cleaning Biological Debris from Materials and Effects of the Cleaning Process on Material Properties

K. Merritt, VM Hitchins, SA Brown, TO Woods, FDA/CDRH/DLS&DMMS, Rockville MD 20852

Devices that have been used on patients can have a variety of biological contaminants including blood cells, proteins, tissue, tissue cells, or micro-organisms. If these devices are to be re-used the debris must be removed before packaging and sterilization or disinfection. If the devices are to be examined as part of an implant retrieval program, they should be handled appropriately. In some cases the presence of biological material is part of the analysis, in some cases the biological material needs to be removed for adequate analysis. In addition the hazards to the personnel handling these devices need to be considered. It was the purpose of the studies described here to determine adequate methods of cleaning materials and devices. It was decided that the biofilm formed by S. epidermidis on polystyrene provided a worst case scenario for testing cleaning efficacy.

Methods: *Organisms*: S. epi RP62A, a known adherent strain, was allowed to grow in 96 well polysytrene culture plates for 24 or 48 hours. The wells were then subjected to cleaning procedures. At the end of the selected procedure, formalin was added to the wells, and then Crystal Violet (0.05%) was added for 5 minutes, the wells washed with water, dried, and the optical density (OD) determined in a plate reader at 540 nm to provide a quantitative measure of cleaning. A reduction in optical OD indicated cleaning. Candida albicans, Pseudomonas, E. coli, and tooth scrapings were also used to test the protocol.

Blood: Sheep blood was used to contaminate the 96 well plate in the same manner as the bacteria.

Cleaning Procedures : A variety of substances were evaluated for their effects. Detergents with and without enzymes, surfactant agents, enzymes, and water were used. Substances with disinfection capabilities including formalin, iodines, ethanol, Regular Clorox™, and Clorox II™ (peroxide based) were also used.

RESULTS OF CLEANING STUDIES: The data obtained indicated that a number of issues that are generally accepted as true were in fact true:

1. S. epi formed a strongly adherent biofilm with Candida also producing an adherent biofilm. The other organisms were not as difficult to clean from the surface.
2. Samples allowed to dry were difficult to clean
3. Detergents with enzymes were effective
4. Detergents without enzymes were not effective
5. Disinfectants "glued" the bacteria to the surface and subsequent cleaning with detergent with enzymes was ineffective;

However: Regular Clorox, (but not CloroxII), was an effective cleaning agent. A 1/10 dilution of Clorox, as recommended on the bottle label for disinfection of surfaces was used. Clorox was also capable of removing the bacteria that had been "glued" down by formalin or allowed to dry.

Recommended Cleaning Protocol: Contact with Clorox for at least 15 minutes, followed by soaking in detergent with enzyme, and then water rinses with water will complete the cleaning process. Since Clorox is known to be a good disinfectant for bacteria, most fungi, and viruses, including HIV, the initial soak in Clorox should render the device safe for handling.

MATERIALS CONCERNS

The recognition that Clorox was an effective cleaning agent and would provide devices safe for handling raised the question as to whether it was safe for the device. It was stated on the labels in our hoods and incubators that Clorox would damage stainless steel, and concerns were also raised about elastomeric materials. Thus studies on the effect of Clorox on representative materials were undertaken.

Metals: Stainless steel (316) was subjected to standard corrosion studies with forward and reverse polarization. This was done with samples that had been in Clorox for cleaning and samples tested directly in Clorox solutions. The corrosion curves produced in Clorox solution were more unpredictable than those in saline or acid. However pitting corrosion and breakdown were observed at levels slightly lower than in standard corrosion solution. Examination of the surface revealed a clean specimen with some pitting. Samples that had been in Clorox and rinsed behaved as other 316 samples not exposed to Clorox. Titanium was tested in Clorox and the surface was clean with no evident damage.

Optical Polymers: Polycarbonate and Plexiglass specimens were subjected to the cleaning protocol and no visible defects were apparent.

Polymers: Latex, nylon, and 80A and 75D polyurethanes were cut into tensile bar specimens and subjected to the cleaning protocol and to simulated contamination using sheep blood followed by cleaning, and to extensive time in Clorox. Mechanical testing revealed material specific changes: latex was not affected, in tensile strength: nylon was weakened a little, 80A was strengthened, and 75D was weakened.

Abstracts for the 2000 FDA science forum from the OST [illegible].

Effects of Use and Reprocessing on Single Use Coronary Catheters. S. A. Brown[1], K. Merritt[2], V. M. Hitchins[2], and T. O. Woods[1]. [1]*Division of Mechanics and Materials Science and* [2]*Division of Life Sciences, CDRH/ FDA, Rockville Md-20852*

Although sold for single use only, some medical devices, such as coronary catheters, are being processed for reuse. Over 400 PTCA and 300 EP catheters have been retrieved after single patient use at Walter Reed Army Hospital. After disinfection and cleaning, a variety of performance characteristics were determined, and then some were subjected to ETO sterilization and simulated reuse. The results demonstrated that cleaning was not a trivial problem. The balloon compliance data demonstrated model specific changes. Some catheters became more sticky making insertion more difficult. Some models of EP's were non-lumen, whereas others had hollow cores sometimes contaminated with blood.. Damage to electrode seals exposed the lumens as well as copper wires connected to the electrodes. Unbeknownst to the user, subtle changes in device appearance may be associated with major changes in the performance of a used or reused device.

Effects of Different Sterilization Methods on Materials Used for Single Use Devices (SUDs) S. A. Brown[1], K. Merritt[2], T. O. Woods[1],and V. M. Hitchins[2]. [1]*Division of Mechanics and Materials Science and* [2]*Division of Life Sciences, CDRH/ FDA, Rockville Md-20852*

Driven by economic and time constraints, some medical centers and third parties are resterilizing SUDs for reuse. The steam autoclave is quick, but most plastics used in SUDs can not survive the temperature. Thus, a number of new methods are being introduced on the market. To date, this program has studied the effects of five: EtO, peracetic acid + peroxide (Steris) , high temp formaldehyde, (Chemiclave), low temp peroxide gas plasma - (Sterrad) , and low temp peracetic acid gas plasma (Abtox). Tensile strength testing has shown that silicone elastomer is unaffected, whereas the strength of nylon, polyethyelene and latex was reduced by some of the methods. Depending on the formulation the strength of polyurethane either increased or decreased. The results demonstrate that the effect of sterilization depends on the method and the materials used in the device.

The Effect of Repeated Ethylene Oxide Sterilization on the Mechanical Strength of Synthetic Absorbable Sutures T.O. Woods[1], S.A. Brown[1], K. Merritt[2], & V.M. Hitchins[2]. [1]*Division of Mechanics & Materials Science,* [2]*Division of Life Sciences, CDRH, FDA, Rockville, MD 20850*

Sutures that are opened but not used are commonly reprocessed for reuse, though they are labeled for single use. The effect of repeated ethylene oxide (EO) sterilization on the knot strength of three types of absorbable sutures was tested. Suture inner packs were repacked and EO sterilized using a clinical protocol. Mean knot strength was measured out of package and after 1 and 2 Re-EO cycles. As is true for other devices, it is not possible to make general conclusions. Suture strength was not affected for some sutures; others increased or decreased in strength. Seals on some inner packs were destroyed during reprocessing, exposing the absorbable sutures to ambient humidity. While seal loss might not cause an initial strength loss, exposure to increased humidity for an extended time will cause suture degradation and loss of strength.

The Effect of Reprocessing on Single Use Electrophysiology Catheters T.O. Woods[1], S.A. Brown[1], K. Merritt[2], & V.M. Hitchins[2]. [1]*Division of Mechanics & Materials Science,* [2]*Division of Life Sciences, CDRH, FDA, Rockville, MD 20850*

Electrophysiology catheters (EPs) are one of the single use devices that are most often reported to be reprocessed and reused. Once it has been established that a used device can be cleaned and resterilized, it is necessary to show that its mechanical behavior has not been adversely affected. Torque and trackability, two clinically relevant mechanical properties of EPs, will be determined for a solid and hollow configuration of one model of EP catheter. The two types reflect a manufacturing change that was made without a change in model name. The two properties will be determined for new, unused catheters; for catheters after use in a single patient; and for used catheters subjected to a number of cycles of ethylene oxide sterilization, simulated reuse and reprocessing cycles. Results for the two catheter types will be compared.

Reprocessing Single Use Biopsy Forceps for Reuse K.Merritt, V.M. Hitchins, S.A. Brown, T.O. Woods *Division of Life Sciences, Division of Mechanics and Material Science, CDRH, FDA, Rockville MD 20852*

Economic considerations in the delivery of health care are enticing some facilities to reuse single use devices. Biopsy forceps, used together with an endoscope in gastrointestinal procedures, are among the devices that some entities are reprocessing. If these forceps are to be reused on another patient, they must be adequately cleaned and sterilized. We have been examining 3 types of single use GI biopsy forceps. These have an external polymer sheath covering the spring that operates either jaws or a snare. The snares have an open lumen. The jaw forceps appear sealed but actually there is an open lumen. Cleaning of these devices with a sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse appears to remove residual debris. However, drying the lumens of these devices is very difficult. Residual water may decrease the effectiveness of sterilization.

Poster Presentation at:
Biofilms 2000
July 19 Big Sky Montana

Biologically Relevant Test Soils and Methods to Detect Residual Soil for Validation of Cleaning Medical Devices

K. Merritt, VM Hitchins, MK Willison, FDA/CDRH/OST/DLS, HFZ 112, 12709 Twinbrook Pkwy, Rockville, MD 20852

Medical devices that have been used on a patient must be cleaned and disinfected/sterilized prior to reuse. Exposure to extraneous biological debris in the second patient must be prevented and sterilization parameters are based on knowing the bioburden. Most medical devices that are reused have short duration (<3 hrs) contact with the patient. Thus the presence of bacterial biofilm on the device after short term use on a patient is not likely. However, if the devices are not cleaned immediately after use, residual bacteria may multiply and form a biofilm. In addition, many other biological residuals, such as tissue, blood, mucus, and lubricants, may be on the device. Many devices have narrow or opaque lumens or other features impeding visual inspection and thus visual observation for cleanliness is not sufficient. In order to validate that a cleaning protocol is effective, both soils that simulate biological material and acceptance criteria (endpoints) to determine that the soil has been removed, are needed. This study examined both bacterial and non bacterial soils and various dyes to develop test soils and endpoints. Bacterial biofilm containing *S. epidermidis* was stained with crystal violet, washed with water; the stain was eluted with alcohol, and the optical density was measured. The detection limit was hard to determine but was less than 1,000 organisms. The most tenacious test soil to simulate biological residuals was a mixture containing 1% hog mucin, 1% egg white, 1% gelatin, and 10% v/v (9.2% wt/v) cottonseed oil (all from Sigma) in distilled water. Various dyes were used to detect and quantify the presence of the test soil. Bradfords reagent (sensitivity level of 4 ug) and Crystal Violet (sensitivity level of 250 ug) were adequate in detecting the protein. Advantages of Bradfords are that (1) protein changes the color of the solution and (2) the dye does not stain the test soil or the device. The hog mucin was detected by Acid Fuchsin with a sensitivity level of 125 ug. The cottonseed oil could be detected by Oil Red O (78 ug), Fat Red (20 ug), Sudan IV (20 ug), and Sudan Black B <10 ug. Cleaning procedures incorporating NaOCl based bleach followed by detergent with enzymes were efficacious for removing bacteria, protein, and hog mucin. Thus far, cleaning methods to successfully remove the cottonseed oil have not been identified and further effort is being directed to this issue.

The Effects of Use and Simulated Reuse on PTCA Balloons and Catheters

Brown, S. A., Merritt, K., Woods, T. O, and Hitchins, V. M.
FDA/CDRH/OST, 9200 Corporate Blvd, Rockville MD, 20850

Introduction. Percutaneous transluminal coronary angioplasty (PTCA) balloon catheters are marketed as single use devices. However, due to economic pressures, some medical institutions are cleaning and resterilizing PTCAs for reuse. The purpose of the present study was to investigate the properties of new and used catheters, and subject them to simulated reuse protocols to identify performance characteristics which might be altered by reuse and reprocessing. Since the objectives of these studies were to identify critical characteristics and to develop test methods to determine which properties of catheter performance are altered, and not to determine what type of catheters are affected, the manufacturer and model identification will not be disclosed in this report.

Methods. A device retrieval program was established with the Division of Cardiology at Walter Reed Army Medical Hospital. New PTCAs donated by manufacturers have also been included in these studies. As a worst case scenario, the medical center personnel were not asked to do any cleaning, but simply to place the catheters after single patient use in plastic bags. The bags were collected biweekly. Catheters were disinfected and cleaned by soaking and flushing with sodium hypochlorite and enzyme detergents. Balloons were flushed repeatedly with water.

Catheters were inspected visually for signs of kinking, balloons were examined with a stereo microscope for evidence of damage. To measure the compliance of the balloons, their catheters were fixed to a stand on an optical comparitor and the balloons inflated with a retrieved inflator. The diameter of a 10x magnification shadow of the balloon was measured with a digital micrometer at 1, 3, 6, 10, and 12 atmospheres (ATM). This sequence was repeated and the second set of numbers used for analysis. The balloons were then repeatedly flushed with water, pumped to remove most of the liquid, and hung up to dry. The measured compliance data were compared with the manufacturer's specifications found on the package inserts. To measure the slipperiness of the catheters, they were threaded through a 21 cm length of 3.2 mm ID PVC tubing. This was then placed on a mounting block to hold it in a 11 cm diameter semicircle and filled with water. The Luer-lok connector was mated to a fixture on the load cell of a universal tensile testing machine, and the catheter pulled at a rate of 25.4 cm/min. To simulate reuse (SIM), catheters were inserted in standard PE shipping sleeves, packaged in sterilizabon pouches, and sterilized in a clinical ETO unit (10% ETO 75-21-8, 90% hydrochlorofluorocarbons, 54C, 50-65% humidity for 130 min, with 12 hr aeration). They were then placed in a bag of sheep blood and inflated to 6 ATM for 2 hours, and then subjected to the standard disinfection and cleaning procedure. A second set of catheters were resterilized (ETO) without simulated reuse.

Results. To date, over 400 catheters have been examined and tested. These include 26 models from 8 major manufacturers. As would be expected, some of the retrievals had kinks in the catheters and some guide wire lumens were plugged with dried blood. Cleaning the balloons has proved to be a consistent problem. If all the radiocopaque dye is not removed, it will form crystals in the balloon when dried, and may also form plugs in the catheter lumen or in the Luer-lok manifold. Some of this cleaning problem could be attributed to our "worst-case" protocol which left the balloons full of dye for up to two weeks. However, the cleaning proved to be model specific. After over 2 years of technique refinement, we still have some models which are consistently plugged when dried, and others which are routinely very clean when dry.

The correlation between measured compliance data and that specified by the manufacturer also was model specific. Some data were within 2% of specifications while others were outside a 10% error band. Data for a subset of three models are shown in Table 1. These are the measured diameters at 10 ATM, expressed as a percentage of the manufacturers' specifications; mean and standard deviation. The changes observed after SIM 2x were significant for both "Z" and "W" ($p<.02$ and $<.0001$, resp), as were the reductions in diameter after ETO 2x ($p<.05$ and $<.0001$). The changes in diameter after SIM 2x for "X" were not significant, and thus the effects of ETO alone were not studied. Models "Z" and "X" were compliant balloons which expanded 0.05 and 0.04 mm/ATM over the range of 3 to 9 ATM. In contrast model "W" was a high pressure noncompliant balloon which expanded only 0.02 mm/ATM. Thus, the small changes after SIM 2x for "W" were considered significant, whereas the similar changes for "X" were not.

Table 1. Compliance of 3 models (Z, W, X) of used balloons after single use (USED), simulated reuse (SIM) 1 and 2 times, and sterilization (ETO). Data expressed as a percentage of manufacturers specifications , at 10 ATM of pressure.

	"Z"	"W"	"X"
USED	93.2 ± 2.1%	101.1 ± 0.9%	99.2 ± 1.4%
SIM 1x	89.2 ± 3.1%	98.9 ± 1.1%	98.8 ± 1.5%
SIM 2x	87.5 ± 3.6%	97.1 ± 0.5%	97.9 ± 1.4%
USED	92.7 ± 1.4%	99.8 ± 0.5%	
ETO 1x	89.7 ± 3.6%	95.3 ± 0.8%	
ETO 2x	88.5 ± 4.1%	94.7 ± 0.8%	

The results of slip testing the catheters were more qualitative in nature. Load versus distance recordings were obtained which showed regions of the catheters where sticking between the catheter and the PVC tubing occurred. New and used model "W" were tested. The load to pull a new "W" through the tubing averaged between 0.2 and 0.4 N. After 1x ETO the new "W" catheters were more sticky with peak loads of 2.5 to 3.5 N, with an average of >1 N for the entire length. The results with used "W" catheters were similar to new ones. After 3x ETO used "W" catheters were very sticky to the touch, and had multiple sticking peaks of 6 to 7 N throughout the entire length. The "X" catheters were less sticky than "W", and showed less effect due to ETO, but they were 0.1F smaller. Used and ETO 2x catheters "Z" of the same size as "X" were very slippery and showed no change with sterilization. The slip coatings on each of the three types of catheters had different trade names.

Discussion. As with any device retrieval and analysis study, this study lacks control over the *in vivo* conditions to which the devices were subjected and the numbers of individual types retrieved. However, in several cases we were able to retrieve sufficiently large sample sizes to permit identification of differences between models. Many of the devices were difficult to clean, perhaps due to drying during storage prior to retrieval, yet model specific differences were noted. In particular, cleaning the dye was often model specific. For example, with one model, 14 out of 25 were plugged with dye, whereas with another model from the same manufacturer only 5 out of 52 were plugged. Unfortunately, there are no standardized test methods to insure that the catheters and open guide wire lumens are cleaned of all bioburden, or that that the balloon and lumen are free of dye.

The data demonstrate that some balloons become less compliant with repeated simulated reuse or ETO sterilization. While some of the changes shown here at 10 ATM may not be clinically significant, several types showed an abrupt change in compliance at higher pressures. Specifically the "W" balloons expanded dramatically between 12 and 16 ATM, whereas the "Z" balloons expanded over a 5 to 15 minute time period when held at 12 ATM. A limited number of the balloons were tested to failure. None of those subjected to simulated reuse failed at pressures below their rated burst pressures. However, the simulated reuse protocol did not subject the balloons to dilation of simulated calcified lesions.

Clearly, the effects of use and reuse are model specific. One can not generalize regarding the effects of reprocessing and reuse on PTCAs as a class.

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Safety and Cleaning of Medical Materials and Devices

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Abstract: A study was undertaken to evaluate different procedures to safely remove microorganisms, protein, and mammalian cells from materials and provide a suitable method for cleaning and assessing effectiveness of cleaning medical devices for reuse or for analysis of failure. Safety considerations for the personnel performing the cleaning or handling the device after cleaning are important issues. Polystyrene plates (96 well) were used to simulate device surfaces not amenable to manual scrubbing. *Staphylococcus epidermidis*, *Candida albicans*, *Escherichia coli*, *Pseudomonas aeruginosa*, and oral flora were grown in the plates. The plates were stained with crystal violet and the optical densities recorded. The results indicated that *E. coli* did not adhere well and *Pseudomonas* formed clumps that were easily detached from the surface of the plates. However, *S. epi*, *C. albicans*, and the oral organisms formed adherent biofilms that were difficult to remove from the plates. Detergents with enzymes and sodium hypochlorite (NaOCl) bleach were both effective in removing the biofilm. Other detergents and surfactants were not effective. The aldehyde agents did not remove the organisms and made further cleaning difficult. Allowing the biofilm to dry first made cleaning very difficult. Only the NaOCl bleach could subsequently remove the dried or aldehyde fixed organisms from the wells. The same 96-well polystyrene plate format was used to measure the amount of protein and cell adherence as well as the effectiveness of subsequent cleaning. Bradford reagent was used to detect protein as a measure of the cleaning efficacy. As with the bacteria, NaOCl bleach was effective at removing the protein and cells that had been dried or fixed by formalin or alcohol, whereas detergent with enzymes was not very effective. This study confirmed that used medical devices, contaminated with microorganisms, protein, and/or mammalian cells, should not be allowed to dry before cleaning and that a thorough cleaning procedure should precede sterilization or disinfection (with the exception of NaOCl bleach which also cleans). © 2000 John Wiley & Sons, Inc. J Biomed Mater Res (Appl Biomater) 53: 131–136, 2000

INTRODUCTION

During the last quarter century, the practice of medicine has moved from the use of (a) items that were cleaned, sterilized, and reused; to (b) single use disposable items; and now to (c) the reuse of disposable single use items that have been cleaned and reprocessed.[1–3] The need to control costs has prompted the reuse of items that were manufactured originally for single use and then disposal.[4] Thus, there is a mix of items being used. Those that are designed to be cleaned and reused, single use devices that are discarded after use, and single use devices that are designed to be discarded after a single use but are being cleaned and reused on the same patient or on different patients.[1–4]

There are three basic safety concerns with reusing medical devices. *First* is the cleanliness and sterility of the device and the subsequent safety to the patient, which also includes issues of cleanliness affecting subsequent the disinfection or sterilization process. *Second* is the effect of cleaning, disinfection, and sterilization on the chemical, physical, and mechanical integrity of the devices. The *third* concern is providing for the safety of the personnel who are responsible for cleaning, disinfecting, or resterilizing the devices. The issue of safe and effective decontamination of devices is also important in device retrieval and analysis.

This study was undertaken to determine the efficacy of various methods used to clean device materials. This brief report describes cleaning clinically relevant microorganisms, protein, and mammalian cells from 96-well polystyrene plates. Although polystyrene is not among the device materials currently being reused, the 96-well format allows quantitative assessment of effectiveness of removing organic materials from surfaces. The results from this study provide data on protocols for cleaning medical device materials for reuse of devices or for analysis of retrieved devices. Sensitive dye techniques are used to assess cleaning, which is defined as the removal of detectable extraneous material.

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ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

July 7, 2000

BY FACSIMILE

The Honorable James Jeffords
Chairman
Health, Education, Labor & Pensions Committee
United States Senate
428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Jeffords:

On behalf of the Association of Disposable Device Manufacturers, I would like to thank you for your interest in the growing practice of single use medical device reprocessing. The June 27th Health, Education, Labor and Pensions Committee hearing on reprocessing has raised public awareness of this important issue and attests to your commitment to protect public health from unsafe reprocessed single use devices. Several participants at the hearing raised questions concerning the significance of the "single use only" label. These questions are indicative of a general lack of understanding regarding the medical device design process. The purpose of this letter is to explain the meaning of the single use label and to clarify some of the misconceptions about medical devices labeled for "single use only."

Designing Single Use Products

Single use devices are designed to be disposable and to perform reliably for a limited use. Ease of cleaning must typically be sacrificed to achieve these goals. To best understand the design process for complex medical devices, it may be easiest to consider the design features of a less intricate, more common product. Imagine a manufacturer of writing surfaces who is contracted to create two different writing surfaces: one that can be disposed of and another that can be reused. The manufacturer would likely design a paper writing surface for the first and a blackboard for the second. As with single use medical devices, the disposability requirement influences the design from the outset and leads to a less expensive product that can not withstand repeated reuse.

The "single use only" label is a meaningful, scientifically sound and accurate designation of a product that is designed and manufactured for use on a single patient. A medical device can only be labeled for what is has been demonstrated to do safely and effectively. Single use devices are cleared or approved by FDA for one use because they have been demonstrated to be safe and effective only when used on a single patient in a single procedure. Reprocessing ignores the fundamental importance of the device design and jeopardizes the health and safety of U.S. patients.

History of Single Use Device Development

Devices are designed to be single use either out of necessity or in response to requests from the medical community. The history behind each of these developments is explained below.

First, some medical procedures require a device so intricate, small or complex that cleanability must be sacrificed to achieve adequate performance properties. In this situation, a reusable model of the device is not possible. The improvement of plastic

technology over the past few decades has allowed medical device manufacturers to design and manufacture devices that are smaller, more reliable in design, and more effective for specific patient needs. Many of the interventional technologies that have revolutionized medicine, such as balloon angioplasty catheters, controlled radial expansion balloons, and tools to repair brain aneurysms, are only possible because of the innovative design features of single use devices. These devices could not be made to achieve their intended purpose if cleanability was also a requirement. For instance, due to the innovation of medical device manufacturers, a patient with clogged coronary arteries does not have to endure the trauma of a double or triple bypass operation. Instead, he can undergo a minimally invasive coronary angioplasty procedure and have a tiny, intricate balloon catheter inserted through a small incision in his groin. The catheter is then snaked through his body into the arteries of his heart where it can restore normal blood flow. This tremendous improvement in patient care is possible only with an extraordinarily complex and delicate device which cannot be properly cleaned and will not function properly if reprocessed.

The second development leading to the design of single use devices is physician demand. In an effort to eliminate the potential for cross-contamination and infection, physicians have requested that certain devices be made economically enough to be disposed of. In this case, both reusable and single use models of a device are often available. The reusable models are designed to be durable and easily disassembled for cleaning, while the single use models are made to achieve their functionality for a much more limited degree of use and are often made of inseparable, molded components. Physicians and hospitals who choose to reprocess should select the reusable device that was designed, manufactured and approved for cleanability. Selecting a single use device and then reprocessing it unnecessarily exposes patients to enormous risk.

Reprocessing Compromises the Safety Margins Built into Single Use Devices

The practice of reprocessing and reusing single use devices disregards the design features of the device. Reprocessing attempts to make cleanability a feature of the single use device despite its absence in device design. Cleanability and functionality cannot be tested into a device – they must be designed in. Testing each device before it leaves the reprocessing shop only demonstrates that the device worked in that test – not that it will work on its next use in the patient. Adequate cleanability cannot be accomplished without seriously affecting device features such as sharpness, material strength, flexibility, dimensions, lubricants, tensile strength, burst pressure, leak pressure, surface finish, and membrane integrity.

In fact, the reprocessor testing merely uses up the safety margin built into these products to protect patients. Think again about the paper writing surface. It has a safety margin built in so that the user can erase a mistake and write on it again. Repeated erasing, however, uses up the safety margin and causes the paper to tear. Similarly, each repeated use and testing brings the medical device one use closer to catastrophic failure inside a patient.

* * * * *

I hope that this letter has clarified the meaning of the single use label. I look forward to working with you and your staff in the future and will keep your staff informed of any progress that is made in reaching a resolution that protects patients.

Again, thank you for you interest in this issue. If you have any questions or if you need any further information, please contact me at 202-737-7554.

Sincerely,

Josephine M. Torrente

JMT/dmb

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April 10, 2000

BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, Maryland 20857

Re: Docket No. 00D-0053

Dear Sir or Madam:

Hyman, Phelps & McNamara, P.C., on behalf of the Association of Disposable Device Manufacturers (ADDM), respectfully submits these comments to the draft guidances entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (FDA Prioritization Scheme) and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (Enforcement Priorities Guidance) both of which were noticed in the *Federal Register* on February 11, 2000 (together, the February 2000 Guidances).[1]

ADDM is a trade association of medical device manufacturers whose mission is to provide information and industry perspectives on issues relating to single use medical devices. Since its formation less than eighteen months ago, ADDM has sought appropriate FDA regulation, including enforcement of the premarket submission requirements, of

[1] See 65 Fed. Reg. 7027 (Feb. 11, 2000).

entities that reprocess single use devices. ADDM is encouraged by publication of the February 2000 Guidances which evidence FDA's movement toward such regulation. ADDM remains concerned, however, that the February 2000 Guidances include gaps that present serious risk to patients. In submitting these comments, ADDM hopes to assist FDA in achieving swift resolution of the few remaining patient safety issues still present in FDA's strategy.

ADDM generally agrees with the FDA's revised approach to regulating reprocessed single use devices, including the enforcement of premarket requirements on reprocessors of all single use devices, the risk-based implementation scheme, and the focus on used, rather than open but unused, single use devices. Most importantly, the February 2000 Guidances require reprocessors of all single use devices, including devices designated as "low" risk under the FDA Prioritization Scheme, to adhere to the premarket requirements of the Federal Food, Drug, and Cosmetic Act (FDC Act). This policy is a substantial change from FDA's Proposed Strategy on Reuse of Single Use Devices, published in November 1999 (the November Strategy), which stated that FDA planned "to exercise enforcement discretion not to enforce 510(k) submission requirements" on devices deemed to be "low" risk.[2] As discussed below, ADDM believes FDA should expressly rescind the November Strategy and finalize the February 2000 Guidances.[3]

In finalizing the February 2000 Guidances however, FDA must address several outstanding issues, each discussed in detail below, that may continue to put patients at risk. Specifically, the FDA must clarify (1) the role of the FDA Prioritization Scheme and the table of devices and risk categories which appears in Appendix B of the Enforcement Priorities Guidance and Appendix 2 of the FDA Prioritization Scheme (the List of Devices), (2) the status of reprocessed exempt single use devices, (3) the implementation timeline, (4) the questions in the FDA Prioritization Scheme flowcharts, (5) statements in the November Strategy regarding single use device labeling, and (6) the content of premarket submissions for reprocessed single use devices. Finally, several inaccurate

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2 See FDA's Proposed Strategy on Reuse of Single Use Devices at 10 (Nov. 3, 1999).

3 The FDA Prioritization Scheme expressly supercedes an FDA guidance document entitled, "Reprocessing and Reuse of Single Use Devices: Risk Categorization Scheme" which was placed on the FDA website on December 8, 1999 and noticed in the *Federal Register* on February 2, 2000, but makes no mention of the November Strategy. FDA Prioritization Scheme at 3.

citations and classifications in the List of Devices require administrative corrections prior to the finalization of the February 2000 Guidances.

A. Role of the FDA Prioritization Scheme and the List of Devices

The FDA Prioritization Scheme identifies general categories of single use devices that FDA believes are frequently reprocessed. Based on the answers to broad questions intended to gauge the level of risk of infection and the risk of inadequate performance after reprocessing, each family of devices is assigned to a "high," "moderate" or "low" risk category. Any device that does not appear on the List of Devices is deemed "high" risk by the FDA Prioritization Scheme.[4]

The stated purpose of the FDA Prioritization Scheme is temporary in nature: to assign a perceived level of risk to each category of reprocessed single use devices and to use that assignment to prioritize the enforcement of premarket submission requirements for those devices.[5] Because of its inability to consider device-specific design and data, the FDA Prioritization Scheme will necessarily be inexact in its assignment of risk designations. ADDM therefore agrees that the FDA Prioritization Scheme does not have any lasting value, but rather, is only useful as an interim measure during the two-year implementation timeframe.[6] ADDM believes that it would be inappropriate for the agency to use the FDA Prioritization Scheme for any future purpose. Any additional use of the FDA Prioritization Scheme would raise concerns about the safety of medical devices and the soundness of the regulatory process due to the overgeneralization inherent in the scheme beyond this interim measure.

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[4] Id. at 2. ("FDA will consider any [single use devices] not on the current list or subsequently revised lists to be one that poses a high risk if it is reprocessed.").

[5] Id. at 2 ("The risk prioritization scheme is intended to help FDA and stakeholders determine the level of risk associated with the reuse of single use devices and the enforcement strategy guidance presents FDA's current thinking on the time table it will use to phase in the enforcement of regulatory requirements for third parties and hospitals that may intend to reprocess these products.").

[6] Under the Enforcement Priorities Guidance, all reprocessed single use devices, regardless of level of risk assigned by the FDA Prioritization Scheme, will be required to comply with the premarket requirements of the FDC Act 2 years after finalization of the Enforcement Priorities Guidance.

ADDM disagrees with FDA's intention to use the FDA Prioritization Scheme "in the future in response to requests from the public on the category of a reprocessed [single use device] not listed" on the List of Devices.[7] Once the FDA Prioritization Scheme is finalized, any devices that do not appear on the List of Devices are appropriately designated "high" risk. Stakeholders who fail to request that FDA add a particular device that is currently being reprocessed to the List of Devices during the current comment period cannot be permitted to submit a future request for designation of an interim risk level. Once the FDA Prioritization Scheme is finalized, the List of Devices is also finalized. FDA should not waste resources reviewing new requests for interim risk designation. Continued revision of the List of Devices would result in confusion over the timing of submissions for various devices, and would encourage reprocessors to submit eleventh-hour comments seeking to down-categorize risk levels.

In addition to devices which are currently reprocessed but do not appear on the final List of Devices, FDA may receive requests to categorize single use devices that are not currently reprocessed, but for which reprocessing may begin in the near future. Because there is no fear of product shortage from single use devices that are not currently reprocessed, these devices should be subject to immediate enforcement action when reprocessing begins.[8] FDA should clarify that a reprocessor who chooses to reprocesses an unlisted device must adhere to all premarket submission requirements within six months of finalization of the February 2000 Guidances.

ADDM also disagrees with FDA's suggestion that the agency should consider promulgating regulations which grant exemptions for devices based on their placement in the "low" risk category by the FDA Prioritization Scheme.[9] ADDM believes that FDA cannot fully determine which devices present an increased risk, and which do not, without review of device- and model-specific data. That is, some reprocessed devices designated as "low" risk by the FDA Prioritization Scheme may actually pose a serious threat to patients. By its very nature, the FDA Prioritization Scheme cannot distinguish among the wide

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7 FDA Prioritization Scheme at 2.

8 FDA lists potential device shortages in hospitals as a key motivation behind the phased-in implementation scheme for premarket submissions. Enforcement Priorities Guidance at 5.

9 Enforcement Priorities Guidance at 2; FDA Prioritization Scheme at 17.

variety of device designs which may exist in any one category. It would therefore be inappropriate for FDA to any make long-term exemption decisions based on the FDA Prioritization Scheme. As the agency itself has recognized, the FDA Prioritization Scheme should only affect the timing of enforcement of premarket requirements.[10] Utilization of the "low" risk designation assigned by the FDA Prioritization Scheme as an indication that a reprocessed device should be considered for permanent exemption from premarket requirements runs counter to FDA's stated intention that the scheme will only be utilized to prioritize enforcement action and not to reclassify devices. The decisionmaking process outlined in the FDA Prioritization Scheme is inappropriate for permanent exemption decisions.

B. Device Exemptions

While the Enforcement Priorities Guidance clarifies that reprocessed single use devices are subject to premarket submission requirements based on their device classification and not on their status as "high," "moderate" or "low" risk under the FDA Prioritization Scheme, it also makes clear that FDA intends to automatically grant premarket exemptions to many reprocessed devices without considering the new questions of safety and effectiveness raised by reprocessing devices which were not designed to be reused.[11] ADDM disagrees with this approach. In the interest of patient safety and regulatory equity, FDA must require premarket submissions for all reprocessed single use devices, even where single use or reusable devices of the same type are exempt from these requirements.

1. FDA's Basis for Exempting Certain Reprocessed Single Use Devices is Fundamentally Flawed

Exemption from premarket requirements must be based on an FDA determination that submission of premarket notifications is not necessary to provide reasonable assurance of safety and effectiveness of the device.[12] The fallacy of automatically granting an exemption to a reprocessed single use device merely because an exemption was granted to the device for one use, or because an exemption was granted to a similar device designed to be reused becomes clear upon noting that the List of Devices contains certain devices that

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10 Enforcement Priorities Guidance at 2.

11 Id.

12 FDC Act § 510(m)(2).

FDA deems "high" risk once reprocessed but which are exempt from premarket regulation. Because of the potential for public harm presented by "high" risk reprocessed devices. premarket submission requirements would normally be applicable to reprocessors of these devices no later than six months after finalization of the February 2000 Guidances. However, reprocessors will not need to submit anything to FDA on that date because of the exemption. The confused message from FDA for these devices then is, "we are so concerned about the high level of risk presented by these devices once reprocessed, that in six months we will demand the submission of . . . absolutely nothing."

FDA has noted that this outcome may be inappropriate for devices designated "high" or "moderate" risk by the FDA Prioritization Scheme.[13] The agency, however, has failed to recognize that, not only is a "high risk exempt" device an oxymoron, but that the occurrence of "high risk exempt" devices highlights a fundamental defect in FDA's chosen regulatory approach to exemptions for reprocessed single use devices. This fundamentally flawed approach cannot be used to extend exemptions, whether the devices are designated "high," "moderate," or "low" risk by the FDA Prioritization Scheme. Instead, FDA must only grant an exemption for a reprocessed single use device through the established rule-making process set forth in §§ 510 and 513 of the FDC Act.

Under this regulatory framework, FDA may grant an exemption to a reprocessed single use device if both of the following criteria are met:

1) FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device such as device design or materials . . . FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors; [and]
2) FDA has determined that
    a) characteristics of the device necessary for its safe and effective performance are well established;[14]

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[13] Enforcement Priorities Guidance at 2. ("If any device designated by the companion Risk Scheme guidance as moderate or high risk is currently exempt from premarket requirements, FDA will propose to amend its classification regulations for those devices to require premarket submissions.")

[14] Under this scheme, FDA cannot immediately exempt <u>any</u> reprocessed single use device because the characteristics for the safe and effective performance of reprocessed devices are not well established as required.

b) anticipated changes in the device that are of the type that could affect safety and effectiveness will
   i) be readily detectable by users by visual examination or other means, such as routine testing, . . . or
   ii) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and

c) that any changes of the device will not be likely to result in a change in the device's classification.[15]

2. FDA's Plan to Extend Existing Exemptions to Reprocessed Single Use Devices is Not Based on Good Science

FDA has granted exemptions for both single use and reusable devices. Neither of these exemptions, however, can be blindly applied to reprocessed single use devices. For devices approved for only one use, the current exemptions were granted without consideration of how reprocessing might affect device functionality or whether the device could be safely and effectively used in more than one person. In fact, an exemption for a single use device is based on use in a single patient. Reprocessing raises new questions of safety and effectiveness that were not factored into the original exemption. Extending the exemption without considering these factors would not serve to protect public health.

Even where the original exemption applies to a reusable device, the exemption cannot automatically be extended to a reprocessed single use device. The reusable device exemption contemplates a device designed to be cleaned and used on multiple patients. The additional risks introduced by attempting to reprocess a device designed without regard to its cleanability were not assessed when granting the exemption. Consider, for example, reusable staplers designed of stainless steel for durability and autoclavability, and able to be disassembled for ease of cleaning. Single use staplers, with their molded plastic and aluminum designs, may not reliably form as many staples, cannot be steam sterilized and may be impossible to clean because of inaccessible parts. These impediments to cleaning were not considered in the original exemption for the reusable stapler and raise new questions of safety and effectiveness which must be addressed in a 510(k) submission.

In either of these situations, extending the exemption from 510(k) requirements to a reprocessed single use device is not in the best interest of patient safety and would amount

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[15] 53 Fed. Reg. 21447, 21448 (June 8, 1988).

to an FDA endorsement of reuse of these products without review of data on their safety and effectiveness.

3. Promulgation of Regulations is Unnecessary for Enforcement of Premarket Requirements

The Enforcement Priorities Guidance notes that FDA will publish proposed regulations to amend the classification of any exempt device designated as "high" or "moderate" risk by the FDA Prioritization Scheme.[16] While ADDM agrees with FDA's recognition that the exemption initially granted for these new single use devices cannot be extended to the reprocessed device, ADDM disagrees with the agency's implication that only a formal rulemaking procedure could serve to avoid an exemption for these products. The original exemptions noted in the List of Devices are limited to devices with "existing and reasonably foreseeable characteristics of commercially distributed devices within that device type" when the exemption was promulgated.[17] The exemptions are therefore mooted by reprocessing because the characteristics of a reprocessed single use device did not exist and were not foreseeable at the time of the original exemption. This is because the characteristics of an exempt reusable device include its design for cleanability and the characteristics of an exempt single use device include its intended single use. Neither covers the reprocessing of a device designed to be discarded after use in one patient.

In the past, FDA has consistently utilized the Limitations of Exemptions when new risks are introduced into an exempt device category. For instance, certain general surgical instruments such as scissors and scalpels were originally exempt devices. When an OEM manufactured these same devices to be several inches longer so that they could be used in laproscopic procedures, FDA instructed the OEM that the exemption no longer applied and the new device required a premarket submission prior to marketing because of the increased risk to patients.[18] Reprocessing single use devices is no different. It presents new questions of safety and effectiveness that change the exemption status of the devices. There is no justification for FDA to treat this situation any differently. Initiation of a rulemaking process will unnecessarily expose patients to reprocessed single use devices

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[16] Enforcement Priorities Guidance at 2-3.

[17] 21 C.F.R. §§ 862.9, 864.9, 866.9, 868.9, 870.9, 872.9, 874.9, 876.9, 878.9, 880.9, 882.9, 884.9, 886.9, 888.9, 890.9, 892.9.

[18] Personal communication with Robert O'Holla, Vice-President of Regulatory Affairs, Johnson & Johnson (Mar. 17, 2000).

which have not been cleared or approved by FDA during the years that would be required to finalize such rules.

4. Regulatory Equity Requires That FDA Not Automatically Exempt Reprocessed Single Use Devices From the Premarket Requirements

FDA has stated that the February 2000 Guidances, once finalized, will apply the same regulatory controls to original equipment manufacturers (OEMs) and reprocessors.[19] This statement is not accurate with respect to exempt devices. Under the scheme set forth in the February 2000 Guidances, a reprocessor could market exempt single use devices for multiple uses without a 510(k) clearance, but the OEM would need a 510(k) clearance to market the same. This is because FDA intends to extend the exemptions granted to the original device to the reprocessed device, but FDA has instructed OEMs that a change in the intended use from single use to reusable requires a new 510(k).[20]

In two guidance documents which address converting a single use device to a reusable device, FDA clearly states that a 510(k) must be cleared before the reusable device can be marketed. The agency makes no distinction between exempt and non-exempt devices, and does not set forth a different requirement for exempt single use devices. This lack of distinction between exempt and non-exempt devices is an appropriate recognition of the inability of the exemption to apply to the reprocessed device. Yet, the February 2000 Guidances propose to allow reprocessors to make this change in intended use without a premarket submission. A change from single use to reusable is a change in intended use of the devices regardless of whether the change is made by an OEM or reprocessor. FDA must require that reprocessors, like OEMs, submit applications for this type of change.

5. FDA Must Allocate the Necessary Resources to Bring all Reprocessed Single Use Devices into Compliance with the Law

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[19] *Reuse of Single-Use Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Commerce*, 106th Cong. (Feb. 10, 2000) (statement of David W. Feigal, M.D., Director, Center for Devices and Radiological Health, FDA).

[20] FDA Guidance, Deciding When to Submit a 510(k) for a Change to an Existing Device at 11. FDA Guidance, Questions and Answers for FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities at 6.

FDA's reluctance to enforce the premarket submission requirements on all reprocessed single use devices in not new. In its November Strategy the agency proposed allowing "low" risk reprocessed devices to remain on the market without 510(k)/PMA submissions. After substantial negative comment and Congressional attention, FDA revised its position in the February 2000 Guidances. In place of devices deemed "low" risk, FDA now proposed to allow reprocessed exempt devices to be used in patients without FDA clearance or approval.

The agency's continued attempts to exclude some reprocessed single use devices from full enforcement appears to be part of its effort to allocate resources based on risk. ADDM agrees that, in light of the need to prioritize resources, devices with the greatest potential for patient injury should be brought into compliance first, followed by devices that are perceived to present a lower risk. ADDM does not agree, however, that some subset of devices should be permanently excused from compliance absent a data-based exemption decision.

FDA should pursue other options aimed at bringing all devices into compliance with the premarket submission requirements. For instance, FDA could modify the implementation timeline as follows:

Device Type	Premarket Submission Due Date
"High" risk (exempt and non-exempt)	6 months after finalization of the February 2000 Guides
"Moderate" risk, non-exempt	12 months after finalization of the February 2000 Guides
"Moderate" risk, exempt	18 months after finalization of the February 2000 Guides
"Low" risk, non-exempt	24 months after finalization of the February 2000 Guides
"Low" risk, exempt	30 months after finalization of the February 2000 Guides

Keeping review deadlines at 6 months for all categories, all reprocessed single use devices would be brought into compliance with the FDC Act within 3 years.

C. Implementation Timeline

The FDA Prioritization Scheme suggests a phased-in implementation timeframe of premarket submission requirements for reprocessed single use devices. The maximum grace period for a given device is determined by identifying its categorization as "high," "moderate" or "low" risk and summing the allowable time for submission of a 510(k) or PMA (6 months, 12 months and 18 months respectively) with the expected FDA review time (6 months for all categories).

ADDM notes that there appears to be a typographical error in the Enforcement Priorities Guidance with respect to "low" risk devices. As written, the Enforcement Priorities Guidance sets out the following timeline for the FDA review portion of the low risk device grace period:

> The applicant receives an FDA order finding the device substantially equivalent and cleared for marketing, or an order approving a premarket approval application within *two (2) years* of the filing date.[21]

The correct timeframe should be "six (6) months of the filing date." This is necessary to conform with FDA's intention to not enforce premarket requirements for a total of two (2) years for "low" risk devices, provided that within eighteen (18) months of the issuance of a final Enforcement Priorities Guidance FDA receives either a 510(k) or PMA submission.[22] The additional six (6) months is the time FDA allows for review of a premarket submission after the eighteen (18) month submission deadline passes.

1. Enforcement Dates

The FDA's implementation timeframe[23] is conceptually similar to ADDM's alternative strategy, but with significantly longer grace periods.[24] The FDA's phased-in

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21 Enforcement Priorities at 16 (emphasis added).

22 Id.

23 See Attachment A for a graphic depiction of FDA's suggested phased-in implementation timeframe. The graph takes into account a typographical error on page 16 of the Enforcement Priorities Guidance.

24 See Letter from Josephine Torrente, Esq., President, ADDM, to FDA Dockets

implementation begins on the date of issuance of a final Enforcement Priorities Guidance. and ends two years later with enforcement against "low" risk reprocessed single use devices with no approved 510(k). During this two-year period, FDA's enforcement against all "high" risk, "moderate" risk, and "low" risk reprocessed single use devices is phased in as reprocessors are required to meet 510(k) or PMA filing deadlines and as FDA approves or denies those premarket submissions. ADDM continues to believe that the agency should adopt shorter timeframes in light of the risks posed to patient safety by reprocessed single use devices.

The following bullet points detail ADDM's understanding of FDA's proposed implementation process:

- Six (6) months after publication of a final Enforcement Priorities Guidance, FDA will take enforcement action against entities that reprocess "high" risk devices for which complete 510(k)s or PMAs have not been submitted (including any devices not appearing in the List of Devices);

- Twelve (12) months after publication of a final Enforcement Priorities Guidance, FDA will take enforcement action against entities that reprocess "moderate" risk devices for which complete 510(k)s or PMAs have not been submitted, **AND** "high" risk devices for which 510(k)s or PMAs have not been approved;[25]

Management Branch (FDA Docket No. 99N-4491) (Dec. 2, 1999). Under ADDM's alternative strategy, all Class III reprocessed devices are immediately subject to FDA's enforcement of premarket submission requirements. Class I and Class II single use devices are respectively granted a 180 or 270 day temporary exemption status from premarket submission requirements to allow for orderly filing of premarket submissions. After the temporary exemptions lapse, all reprocessed Class I and Class II devices would be required to comply with the premarket submission requirements.

[25] The Enforcement Priorities Guidance states that the six month FDA review clock for high, moderate and low risk devices begins to run when the 510(k) or PMA is filed rather than submitted. This would lengthen the grace period for these devices by inserting a 45-day window between the expiration of the submission clock and the initiation of the review clock. In this case, the total grace periods would be 13.5 months, 19.5 months and 25.5 months for "high," "moderate" and "low" risk devices respectively. This is inconsistent with the remainder of the Enforcement Priorities Guidance and should be corrected by FDA.

- Eighteen (18) months after publication of a final Enforcement Priorities Guidance, FDA will take enforcement action against entities that reprocess "low" risk devices for which complete 510(k)s have not been submitted, AND "moderate" risk devices for which 510(k)s or PMAs have not been approved; and

- Twenty-four (24) months after publication of a final Enforcement Priorities Guidance, FDA will take enforcement action against entities that reprocess "low" risk devices for which 510(k)s have not been approved.

FDA should clarify that this timing is what was intended by the agency.

The Enforcement Priorities Guidance is unambiguous as to the regulatory status of a reprocessed single use device once one implementation phase ends and another begins. Regardless of FDA's denial of a premarket submission or failure to complete a premarket submission review, ADDM anticipates that a reprocessor that continues to ship single use devices in interstate commerce beyond the dates set forth above will be subject to agency enforcement. After a phase has lapsed, no product in that category should be allowed to be shipped.

FDA states in its Enforcement Priorities Guidance that "the agency may continue to exercise its discretion to not actively enforce FDA requirements for longer periods of time than described [in the Enforcement Priorities Guidance] when there may be shortages of medically necessary devices or for other compelling reasons."[26] The agency does not explain what "other compelling reasons" might invoke agency enforcement discretion. The FDA is responsible for ensuring that all devices, including reprocessed single used devices, are safe and effective for each patient use. Because of FDA's history of inaction on this issue, ADDM is concerned that the agency may invoke this clause to delay enforcement. ADDM can think of no reason compelling enough to forego patient safety. Moreover, the FDC Act does not allow FDA to waive the need for FDA clearance based on unspecified "other compelling reasons."

D. FDA Prioritization Scheme Flowcharts

On December 8, 1999 FDA placed on its website a draft guidance document entitled "Reprocessing and Reuse of Single-Use Devices: Risk Categorization Scheme" (December

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[26] Enforcement Priorities Guidance at 14-15.

1999 Guidance) which contained flowcharts designed to assess risks posed by reprocessed single use devices. This guidance was formally announced in the *Federal Register* on February 2, 2000. That draft guidance was rescinded by FDA nine days later and replaced with the FDA Prioritization Scheme.[27]

The FDA Prioritization Scheme substantially changes the flowcharts in the original guidance document without addressing many of ADDM's comments. The changes appear uniformly aimed at decreasing the number of devices designated as "high" risk, thereby delaying enforcement action for many devices.

ADDM notes that the flowcharts are intended to assess the risk of various categories or groups of devices, and will not be used to make model-by-model determinations of risk. While ADDM agrees that FDA should proceed in this manner, it is important, in the interest of patient safety, that each question in the flowcharts be answered with respect to the model of the device which would result in the highest risk categorization because of its complexity or difficulty to reprocess. While this may result in a few models that would otherwise be deemed "low" or "moderate" risk being placed into a higher risk category, any other approach would result in unapproved or uncleared "high" risk devices remaining on the market for too long.

ADDM's previous detailed comments included revisions of FDA's earlier flowcharts. ADDM continues to advocate use of the flowcharts provided with those comments. Nonetheless, detailed comments on the revised FDA flowcharts are provided below.

1. Flowchart 1 – Infection Risk

Flowchart 1 focuses on risk of infection to patients, but fails to consider the potential risk to infection of healthcare workers exposed to reprocessed single use devices. Each question in the flowchart should consider the healthcare worker as well as the patient.

Question two asks whether post-market information suggests an increased risk of infection for the reprocessed single use device over a new single use device. ADDM agrees

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[27] Because no docket had been created for comments to the December 1999 Guidance for nearly two months after its issuance, ADDM submitted comments to that guidance and its flowcharts in conjunction with its detailed comments on the November Strategy. These comments were submitted to FDA Docket No. 99N-4491 on Feb. 1, 2000. (Attachment B.)

that the existence of any post-market information indicating a potential infection risk for any reprocessed model of a device should cause that category of devices to be deemed "high" risk. FDA appropriately lists "published data, laboratory reports and reports to FDA" as examples of post-market data.[28] ADDM is concerned, however, about how FDA will implement this analysis. With respect to cardiac ablation catheters, FDA states that it is not aware of "any postmarket data on cardiac ablation catheters that suggest that using the reprocessed catheter may present an increased risk of infection when compared to" a new catheter.[29] ADDM is dismayed at the agency's continued failure to recognize the volumes of scientific data generated by its own Office of Science and Technology, and data submitted by ADDM. ADDM has submitted multiple reports of electrophysiology catheters contaminated with residual tissue. Bacteria residing within such tissue may not be destroyed by sterilization attempts. While these reports are not from controlled clinical trials comparing new to reprocessed catheters, they do "suggest that using a reprocessed catheter may present an increased risk of infection" over a new device since a new catheter has never been exposed to patients and therefore cannot be expected to be contaminated with tissue and bacteria.

Question three asks whether the device includes any features that could impede thorough cleaning and adequate sterilization/disinfection. ADDM agrees that this question is appropriate but believes that any device containing such features must be automatically deemed "high" risk. ADDM notes that FDA lists narrow lumens and interlocking parts as examples of such features. FDA should also include inaccessible parts, rough or porous surfaces, inability to be disassembled and the existence of any antimicrobial materials, coatings, or components.

Questions four through six did not exist in the original flowchart in the December 1999 Guidance and should be deleted. Their addition serves only to recategorize some "high" risk devices into "moderate" or "low" risk.

Moreover, Question four is flawed; it must be answered "no" for every reprocessed single use device. The question asks whether a reusable device exists with the same intended use and equivalent design as the single use device. FDA, however, has recognized that "single use" and "reusable" are themselves different intended uses. Thus, no reusable device could have the same intended use as a single use device.

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[28] FDA Prioritization Scheme at 5.

[29] Id. at 18.

In terms of design equivalence, FDA fails to explain the criteria for an "equivalent design." The substantial equivalence standard used in 510(k) review is not applicable. For example, the predicate device in a 510(k) for a single use stapler may be a reusable stapler. This is not to say, however, that the designs are equivalent for reprocessing. The reusable stapler, which is designed for easy access to all parts of the device, cannot predict the cleanability of the one-piece, molded disposable. In addition, FDA fails to explain how it would apply Question four to different models of the same device. It seems that FDA would need to find an equivalently designed reusable device for every model of single use device in the category.

Question five introduces consensus standards into the risk categorization process. As discussed in ADDM's previous comments, the existence of consensus standards should be part of a device's 510(k) review process, but cannot supplant the need for a 510(k), even temporarily, for a reprocessed single use device.

2. Flowchart 2 – Risk of Performance Failure

Question one of the flowchart asks whether post-market information suggests an increased risk of injury for the reprocessed single use device over the new single use device. As with Flowchart 1, any post-market information indicating a potential risk of injury for any reprocessed model of a device should result in that category of devices being designated "high" risk.

Question two did not exist in the original flowchart and should be deleted. This question asks whether failure of the device could lead to death, serious injury or permanent impairment. All device failures put patients at higher risk of injury, even if only because the procedure time is lengthened while a new device is prepared. Each such occurrence amounts to a medical error with the potential of causing serious harm.

Question three appropriately asks whether device performance might be adversely affected by the original use or by reprocessing. However, as noted in ADDM's earlier comments, a positive response to this question should result in a "high" risk categorization and should end that arm of the flowchart. Conversely, a negative response should result in a "low" risk categorization and end the second arm of the flowchart. Questions four and five (and questions 2a and 2b which are identical to four and five) inappropriately introduce consensus standards and the ease of visual inspection into the decisionmaking. These issues may play a role in the device's 510(k) submission and review, but can not be used in a generalized flowchart to determine risk.

E. Device Labeling

Unlike FDA's November Strategy, the February 2000 Guidances do not mention expanded labeling requirements for manufacturers of single use devices. Nonetheless, ADDM is concerned by a recent trade press report that FDA intends to reintroduce labeling issues into the finalized guidances.[30] ADDM comments to the November Strategy demonstrate why this approach should not be adopted.[31]

As stated in ADDM's previous comments, any requirement that the OEM demonstrate the device's inability to be reprocessed or that the original device label include specific information regarding reprocessing is inconsistent with patient safety, public policy and the FDC Act. Requiring a manufacturer to "justify" the single use label by demonstrating that the device cannot be reprocessed would lead to an absurd result. For the first time, manufacturers would be directed to prove the lack of safety of an unintended potential product use. Reassessing the burden in this way stands the FDC Act on its head.

F. Content of 510(k)s

The FDA's February 2000 Guidances do not identify the data and information a reprocessor must submit in a 510(k) for a reprocessed used single use device. ADDM recommends that FDA adopt ADDM's proposed "Draft Guidance Outline for Premarket Review Parameters: Reuse of Used Single Use Disposable Devices," originally submitted to the agency on September 28, 1999.[32] The proposed draft guidance sets forth the cleaning, reprocessing parameters, design and component controls, resterilization methods, device testing, and packaging and labeling data and information a reprocessor must submit as part of a 510(k). ADDM's proposed draft guidance is based on FDA's current requirements for 510(k)s, as expressed in FDA guidance that specifically address reusable devices. Submission of this data and information will ensure that all reusable devices cleared by FDA meet the same standards, whether they are marketed by an OEM or a single use device reprocessor.

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30 *Devices and Diagnostic Letter*, Vol. 27, No. 8, at 1-2 (Feb. 25, 2000).

31 ADDM Comments at 40 (Feb. 1, 2000).

32 ADDM resubmits this draft guidance as an attachment to these comments. See Attachment C.

G. Administrative Corrections

The List of Devices contains several errors. Attachment D to these comments notes the errors contained in FDA's List of Devices and proposes corrections FDA should consider for a final draft of the list. Additions to the list are highlighted (e.g., ***870.1220***), removals appear with a strikethrough (e.g. ~~870.1120~~).

* * * * *

ADDM appreciates the opportunity to submit these comments and looks forward to working closely with FDA to ensure swift implementation of a patient-focused policy on reprocessed single use devices.

Respectfully submitted,

Josephine M. Torrente

JMT/dmb
Attachment

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John Hargraves
Joshua Berlin

Attachment A

Timetable for Premarket Submission Requirements for Reprocessors

Timeline for Premarket Submission Requirements for Reprocessors of Single Use Devices
PERIOD OF CONTINUED
FDA ENFORCEMENT DISCRETION
Enforcement begins against "low risk" reprocessed single use devices with no approved 510(k) or PMA
Enforcement begins against "moderate risk" reprocessed single use devices with no approved 510(k) or PMA
Enforcement begins against "low risk" reprocessed single use devices with no submitted 510(k) or PMA
Enforcement begins against "high risk" reprocessed single use devices with no approved 510(k) or PMA
Enforcement begins against "moderate risk" reprocessed single use devices with no submitted 510(k) or PMA
Enforcement begins against "high risk" reprocessed single Use devices with no submitted 510(k) or PMA
Publication of Enforcement Priorities Guidance
.5 yr.
1 yr.
1.5 yr.
2 yr.
2.5 yr.
3 yr.

Attachment B

ADDM Comments to November 1999 FDA Proposed Strategy

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February 1, 2000

BY HAND DELIVERY

Food and Drug Administration
Dockets Management Branch (HFA-305)
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Rockville, Maryland 20857

Re: Docket No. 99N-4491

Dear Sir or Madam:

Hyman, Phelps & McNamara, P.C., on behalf of the Association of Disposable Device Manufacturers (ADDM), respectfully submits these comments in response to the Notice entitled, "FDA's Proposed Strategy on Reuse of Single Use Devices"[1] (hereinafter, FDA Proposed Strategy) and the subsequent Draft Guidance entitled, "Reprocessing and Reuse of Single Use Devices: Risk Categorization Scheme"[2] (Risk Categorization Guidance).

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1 See 64 Fed. Reg. 59782 (Nov. 3, 1999).

2 See Draft Guidance: Reprocessing and Reuse of Single Use Devices: Risk Categorization Scheme, Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH), FDA (Dec. 9, 1999).

ADDM is a trade association of medical device manufacturers dedicated to providing information and industry perspectives on issues impacting single use devices.[3] ADDM's goal is to bring about the appropriate regulation of reprocessed single use devices. Such regulation will ensure patient safety, conform to the Federal Food, Drug, and Cosmetic Act (FDC Act),[4] demonstrate regulatory fairness, and result in proper allocation of U.S. Food and Drug Administration (FDA or the agency) resources. ADDM has previously submitted an alternative strategy on the regulation of single use device reprocessing (ADDM Strategy) to this docket.[5] ADDM continues to believe that the ADDM Strategy should be implemented in lieu of the FDA Proposed Strategy. Nonetheless, this submission provides general comments on the FDA Proposed Strategy followed by comments addressing each of its eight specific components.

I. General Comments

A. Single Use Devices that are Reprocessed Must be Regulated as Reusable Devices

The Medical Device Amendments of 1976 (MDA) were designed to protect patients from unsafe and ineffective devices, whether single use or reusable.[6] Reprocessing a single use device changes the intended use of that device from single use to multiple use, rendering reprocessors manufacturers of reusable devices. Appropriate regulation of disposable medical device reprocessing would therefore involve enforcement of all provisions of the FDC Act applicable to reusable devices.

Despite FDA's recognition that Congress intended reprocessors to be subject to the same legal requirements as other manufacturers, the agency has, without justification,

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[3] The term "single use device" is used throughout this comment to mean a medical device labeled or otherwise intended by its manufacturer, and cleared or approved by FDA, to be used in a single patient during a single procedure.

[4] See Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq. (1994)).

[5] See Letter from Josephine Torrente, Esq., President, ADDM, to FDA Dockets Management Branch (FDA Docket No. 99N-4491) (Dec. 2, 1999).

[6] Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 15 U.S.C. § 55 and 21 U.S.C. §§ 31, 331).

refused to enforce certain key safety controls on reprocessors. [7] This refusal exposes the American public to medical devices whose safety and effectiveness are, at best, unknown. The FDA Proposed Strategy perpetuates this regulatory inaction for many reprocessed disposable devices putting the FDA Proposed Strategy at odds with the agency's congressional mandate to protect patients from unsafe and ineffective medical devices. No rationale designed to protect public safety can support FDA's continued failure to enforce premarket controls for all reprocessed single use devices.

Unlike the FDA Proposed Strategy, the ADDM Strategy recognizes reprocessed single use devices for what they are: reusable devices. Moreover, the ADDM Strategy safeguards patients by requiring premarket clearance or approval of all reprocessed single use devices. Safety is ensured through FDA regulations, guidances, policies, and enforcement practices already developed for oversight of reusable medical devices. Complying with both the letter and the spirit of the FDC Act, the ADDM Strategy allows for exemption from premarket controls only after FDA reviews data in conjunction with a publicly available petition for exemption. Like all other reusable devices, those reprocessed single use devices for which there is a demonstrated lack of risk would be exempted from premarket submission, thus properly allocating FDA's resources to higher risk products. FDA's implementation of the ADDM Strategy would achieve the parallel goals of increased patient safety, conformance with the FDC Act, parity in regulation of manufacturers, and conservation of agency resources.

B. The FDA Proposed Strategy is Inconsistent with the Requirements of the FDC Act and the Administrative Procedures Act (APA)

1. The FDC Act requires premarket submissions for reprocessed single use devices

The FDC Act requires that, prior to their introduction into interstate commerce, all new medical devices must be FDA-cleared or approved through the premarket notification

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[7] See Letter from Larry Spears, Director, Division of Enforcement III, Office of Compliance (OC), CDRH, FDA, to Stephen Terman, Esq., Olsson, Frank & Weeda, P.C. (July 9, 1999) ("Third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, including premarket notification requirements. FDA has exercised and will continue to exercise regulatory discretion for all premarket notification requirements.").

(510(k)) or premarket approval (PMA) process. This process requires submission of data by the party that intends to market the device. For a single use device. the original equipment manufacturer (OEM) demonstrates that the device is safe and effective for use on a single patient in a single procedure, and the device is therefore cleared/approved for only that use. Reprocessing significantly modifies a single use device by changing its intended use to multiple use. Manufacturers of reusable devices, including single use device reprocessors, are required to submit a new 510(k) or PMA, including data to support the safety and effectiveness of the device for multiple use, prior to marketing the device for use in other patients.[8] While FDA agrees that reprocessors of single use devices are manufacturers under the FDC Act and its implementing regulations,[9] and, as such, reprocessors are subject to the provisions of the FDC Act that require manufacturers to obtain clearance of a 510(k) or approval of a PMA,[10] the agency has clearly announced its intention to permit reprocessed single use devices to be marketed without its clearance/approval, and has subjected them only to some degree of *post*-market regulation. In a July 9, 1999 letter, FDA noted that, "third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, *including premarket notification requirements*." However, "FDA has exercised and will continue to exercise regulatory discretion for all premarket

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[8] Guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device, ODE, CDRH, FDA, at 10-11 (Jan. 10, 1997).

[9] See supra note 7; FDC Act § 510(a)(1), 21 U.S.C. § 360(a)(1); 61 Fed. Reg. 52602 (1996). Although the FDC Act does not globally define the term "manufacturer," various provisions of the Act authorize FDA to regulate the manufacturers of medical devices. For example, the establishment registration and device listing requirements set forth in section 510 apply to any entity engaged in the "manufacture, preparation, propagation, compounding or processing" of devices for commercial distribution. In the 1996 Quality System Regulations (QSR), FDA developed its own definition of the term "manufacturer" as "any person, [including any repacker and/or relabeler] who designs, manufactures, fabricates, assembles, or processes a finished device." 61 Fed. Reg. at 52656. In the QSR, FDA acknowledged that reprocessing entities fall within the broad definition of manufacturers, as intended by the FDC Act.

[10] See 21 C.F.R. Part 807, Subpart E and Part 814 (1999).

notification requirements."[11] This unjustified use of enforcement discretion is perpetuated for many reprocessed single use devices under the FDA Proposed Strategy.

The MDA requires pre-clearance by all device manufacturers, whether they are OEMs or reprocessors. The MDA was enacted for the purpose of implementing *pre*-market review of devices because Congress was concerned that post-marketing regulation of medical devices was inadequate to protect public health.[12] The design of the MDA reveals Congress' belief that post-market controls are insufficient to regulate medical devices. In today's world of increasingly complex medical devices and heightened concern over disease transmission, the regulatory discretion FDA has proposed to use under the FDA Proposed Strategy, is inconsistent with Congress' intent. In enacting the MDA. Congress' goal was to protect patients from unsafe and ineffective devices, regardless of the identity of the device's manufacturer. As such, there is no justification for a patient to receive less protection from FDA merely because the device used for the patient's treatment was a reprocessed single use device rather than an FDA-cleared reusable device. FDA is. in effect, creating a *de facto* exemption from the premarket review requirements for most reprocessed single use devices – and in doing so, is violating its congressional mandate.

2. The APA requires that FDA regulate similarly situated parties in similar fashion

Under the APA, a court may review and hold unlawful an agency decision that is arbitrary or capricious.[13] Under the "arbitrary and capricious" standard, courts have held that treating two similarly situated companies in a different manner is a violation of the APA. In the area of single use devices, FDA has disparately treated two similarly situated parties –OEMs and reprocessors– as exemplified by FDA's inconsistent enforcement of the premarket controls.

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11 Letter from Larry Spears, Director, Division of Enforcement III, OC, CDRH, FDA to Stephen Terman, Esq., Olsson, Frank and Weeda, P.C. (July 9, 1999) (emphasis added).

12 See H.R. Rep. No. 94-853 (1976).

13 See 5 U.S.C. § 706(2)(A) ("The reviewing court shall . . . (2) hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. . . .").

For example, in order to market a single use surgical stapler for use in multiple patients, an OEM must first obtain clearance of a 510(k) from FDA. A reprocessor that wishes to market that same stapler for use in multiple patients is currently free to do so without a 510(k). Not only is this dichotomy arbitrary, it is also illogical since the OEM has full knowledge of the design criteria and specifications of the device and is in a far better position than the reprocessor to determine whether the device can be reused. When asked what the OEM's regulatory obligation would be if the OEM merged with the reprocessing company that reprocesses the OEM's stapler, FDA responded that the OEM "would have a problem."[14] While FDA did not expand on what that problem might be, there are at least two possibilities. First, because of the lack of a cleared 510(k), the OEM's new reprocessing subsidiary might not be permitted to continue reprocessing the OEM's staplers, yet it might be permitted to reprocess single use devices made by other companies. Second, and equally absurd, the OEM, through its ownership of the reprocessor, might be permitted to reprocess its own single use devices without a 510(k) clearance, yet it might not be permitted to label them for multiple use. Both situations underscore the unfair and illogical nature of FDA's position.

In Federal Election Comm'n v. Rose, the United States Court of Appeals for the District of Columbia held that, "an agency's unjustifiably disparate treatment of two similarly situated parties works a violation of the arbitrary-and-capricious standard."[15] Such behavior by federal agencies is prohibited by the APA.[16] By assigning unequal regulatory burdens to OEMs and reprocessors, FDA violates this principle. Recently, in Bracco Diagnostics, Inc. v. Shalala, the United States District Court for the District of Columbia addressed a situation where FDA applied different premarket review standards to two similar products.[17] Bracco, the manufacturer of an injectable contrast imaging agent, successfully challenged FDA's determination that its product should be regulated as a drug, while a competitor's similar product was classified under the regulatory regime of a device. The court, enjoining any action on these products until FDA decided on a uniform

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14 Remarks made by Casper Uldricks, Special Assistant to the Director, OC, CDRH, FDA, at the FDLI/FDA 42nd Annual Educational Conference (Dec. 16-17, 1998) (transcript unavailable).

15 806 F.2d 1081, 1089 (D.C. Cir. 1986) (citation omitted).

16 See 5 U.S.C. § 706(2)(A).

17 See 963 F. Supp. 20 (D.D.C. 1997).

regulatory regime. held "[t]he disparate treatment of functionally indistinguishable products is the essence of the meaning of arbitrary and capricious."[18]

FDA acknowledges that it "has not regulated OEMs, third-party reprocessors. and health care facilities in the same manner with respect to [single use devices]."[19] In the FDA Proposed Strategy, FDA lists the seven requirements of the FDC Act to which OEMs must adhere: 1) registration and listing; 2) premarket notification and approval requirements; 3) submission of adverse event reports under the Medical Device Reporting (MDR) regulation; 4) manufacturing requirements under the Quality Systems Regulation (QSR): 5) labeling requirements; 6) Medical Device Tracking; and 7) Medical Device Corrections and Removals.[20] Of these requirements, FDA acknowledges that reprocessors have only been subject to four –registration and listing, QSR,[21] labeling requirements, and MDR reporting requirements.[22] This discrepant treatment by itself violates the APA. Moreover, the

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18 See id. at 28 (citation omitted); see also United States v. Diapulse Corp. of America, 748 F.2d 56, 62 (2d Cir. 1984) (holding that FDA must act "evenhandedly" and may "not 'grant to one person the right to do that which it denies to another similarly situated.'"); Willapoint Oysters, Inc. v. Ewing, 174 F.2d 676, 697 (9th Cir.), cert. denied, 338 U.S. 860 (1949); Int'l Rehabilitative Sci., Inc. v. Kessler, Civil No. SA-93-CA-0242, slip op. At 23 (W.D. Tex. June 28, 1993) (finding that FDA's "divergent treatment" of the devices was "glaring evidence of arbitrary action.").

19 FDA Proposed Strategy at 4.

20 See id.

21 While FDA has acknowledged that reprocessors of single use devices must comply with the QSR, the agency has failed to address how compliance can be possible in certain instances. For example, a reprocessor may not be able to verify that devices continue to function safely post-reprocessing. This is because the reprocessor does not have sufficient knowledge of the device's design to determine which functional tests must be carried out or to know the acceptable range of outcomes for those tests. A reprocessor's verification of only those specifications listed on the device's labeling is insufficient to assure safety and effectiveness of that device.

22 That reprocessors are currently not required to comply with even the Medical Device Correction and Removals regulation is particularly telling since this is one of FDA's most important conduits for receipt of adulterated or misbranded device information having safety ramifications (i.e., Class I and Class II recalls). In addition, even the four requirements that FDA lists as applicable to reprocessors are not generally

requirement of greatest consequence and complexity, and the one most important for patient safety –the premarket notification and approval requirement– is not being enforced against reprocessors. The FDA Proposed Strategy violates the APA by continuing to treat reprocessors and OEMs differently. Specifically, the FDA Proposed Strategy will require premarket submissions for OEMs to change any single use device to reusable, but only imposes preclearance requirements on reprocessors for certain single use devices.

This disparate treatment seriously compromises public safety. Devices are being marketed that have not been demonstrated safe and effective as required by law. FDA is effecting a double standard that lowers the burden for reprocessors as compared to OEMs and thus, amounts to arbitrary and capricious activity under the APA. The APA and the protection of U.S. patients both require that FDA regulate all manufacturers in the same manner, regardless of whether those manufacturers are deemed OEMs or reprocessors.

C. Scientific Evidence of Risk to Patients

The FDC Act establishes a presumption that all medical devices are unsafe, and requires that the safety and effectiveness (or substantial equivalence) of new devices be affirmatively demonstrated prior to their entrance into interstate commerce.[23] In addition, FDA regulations have established that substantially modified devices should be regulated as new devices. Claiming that a single use device may be reused causes the device to be

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complied with by the reprocessing industry. Only seven of the over twenty existing reprocessors are registered with FDA, and it is not clear whether even those seven provide device lists. Reprocessed device labels do not typically contain necessary information such as applicable latex warnings and proper instructions for use. Because the OEM's name, not the reprocessor's name, appears on the reprocessed device, most adverse events are reported to the OEM by the hospital, resulting in very few MDR reports from reprocessors.

23 See United States v Bowen, 172 F.3d 682, 687 (9th Cir. 1999) ("The procedure for classifying devices initially places *all* new devices in class III.") United States v. An Article of Device . . . Stryker Shoulder . . . Ligament Prosthesis, 607 F. Supp. 990, 998 (W.D. Mich 1985) ("A 'new device' . . . is automatically placed in the class III category, and immediately triggers the requirement for premarket approval.") (citation omitted). See H.R. Rep. No. 94-853 (1976) at 40 ("Under the proposed legislation, the burden of providing evidence substantiating the safety and effectiveness of a medical device rests upon the manufacturer.").

treated as a new device under FDA's regulatory scheme.[24] Yet, for years FDA has thwarted this clearly stated congressional intent by allowing reprocessed single use devices to be used on patients without requiring or reviewing the necessary data. Instead, FDA determined that it need not take action until it is presented with "clear evidence that reprocessing presents an unreasonable and substantial risk of illness or injury"[25] –a standard quite different from the one established by Congress.[26]

FDA first evidenced its intent to circumvent the FDC Act when it refused to require that reprocessors demonstrate safety and effectiveness of their products, but instead suggested that OEMs provide data regarding the risks associated with reprocessing.[27] Although FDA's shifting of the burden was improper, the OEM industry expended substantial effort to test reprocessed single use devices. The data from that testing, all of which has been submitted to FDA, overwhelmingly indicates serious safety concerns. In addition, FDA's Office of Science and Technology (OST) simultaneously generated its own independent data confirming the risks of reusing certain single use devices. FDA has consistently ignored the OEM studies and has sought to discredit its own data.

In addition to the studies performed by OEMs and OST, additional data has been generated by independent hospital studies, by published literature reports, and by actual patient injuries and device malfunctions reported to FDA through the MedWatch system. Despite the volume of such data on file at FDA, officials at the CDRH have publicly claimed that there is little or no credible scientific evidence available demonstrating that the

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24 21 C.F.R. Part 807, Subpart E; Part 814.

25 Letter from David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA, to Larry Pilot, Esq., McKenna and Cuneo, L.L.P. at 1 (Oct. 6, 1999) (FDA Docket No. 99P-1516) (responding to MDMA citizen petition requesting FDA to ban reprocessed single use devices).

26 See United States v. 789 Cases of Latex Surgeons' Gloves, 799 F. Supp. 1275, 1286 (D.P.R. 1992) ("[A]fter-the- fact regulatory action would offer little or no protection to those members of the public already exposed to – or harmed by – unsafe or ineffective medical devices.").

27 Letter from Bruce Burlington, M.D., Director, CDRH, FDA, to Nancy Singer, Esq., Special Counsel, HIMA, at 2 (July 15, 1998) (FDA Docket No. 97P-0377) ("[W]e are encouraging...OEMs...to provide any data demonstrating adverse patient outcomes from the use of reprocessed 'single use only' devices.").

reuse of disposable medical devices is unsafe. At FDA's November 1999 videoconference, in response to a question regarding FDA's knowledge of such data, the Director of OST stated that, "we haven't had any formal submissions of data on which to make a call for reuse decisions."[28] This statement is a serious mischaracterization of the ADDM studies and other scientific submissions filed with CDRH over the past year and misleads the public. On November 22, 1999, ADDM submitted sixteen abstracts summarizing key studies that had previously been submitted to, or conducted by, FDA.[29] These abstracts verify that FDA has valid scientific data on file confirming the physical, microbiological, and functional performance failures associated with reuse of used single use devices.

1. Stakeholder data

At least nineteen scientific studies involving approximately 1000 individual devices have been submitted to FDA on this topic.[30] These studies have been conducted by independent scientists, hospitals, OEMs, and, as mentioned above, FDA's own laboratory personnel. Many of the devices used in these studies were obtained directly from hospital shelves where they were "ready for use" in seriously ill patients (e.g., patients suffering from cancer, heart disease, and requiring major abdominal, cardiovascular or thoracic surgery).

Devices studied included biopsy forceps, angioplasty balloon catheters, electrophysiology catheters, surgical trocars, staplers, papillotomes, and other general surgical instruments. Approximately 75% of the samples studied failed, either due to the presence of blood and/or proteinaceous matter, bacterial contamination, non-functionality, or defective packaging. In each of seven studies with reprocessed biopsy forceps, a lack of sterility assurance was reported in over 45% of the samples tested. This particular failure

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28 Statement of Donald Marlowe, Director, OST, CDRH, FDA, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel I) (Nov. 10, 1999) (videotape on file at Hyman, Phelps & McNamara, P.C.).

29 See Letter from Josephine Torrente, Esq., President, ADDM, to David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA (Nov. 22, 1999).

30 It is interesting to note that, while minimizing these nineteen studies, the FDA, in promulgating its final rule on labeling for devices containing latex, relied on only four studies to conclude that "there are numerous reports that levels of natural latex proteins found in dry rubber can cause allergic reactions." 62 Fed. Reg. 51021, 51023 (Sept. 30, 1997).

was not unexpected. As recently as last October, FDA issued a warning letter to one of the largest commercial third-party reprocessors, not only citing major QSR violations, but specifically citing the reprocessor's failure to adequately validate the sterilization process.[31] These nineteen separate studies clearly demonstrate that reusing a single use device may seriously compromise the integrity and subsequent safety and efficacy of that device.

2. FDA data

CDRH's failure to recognize and respond to the patient safety issues raised by these data is compounded by its recent attempts to minimize or discredit the results of studies performed in the OST. At FDA's November 1999 videoconference, FDA responded to questions about these studies by dismissing them, stating that they were not intended to be exhaustive.[32] However, in numerous other contexts, FDA has taken enforcement action or directed that recalls be initiated based on anecdotal or scattered reports. FDA's failure to concede, at the very least, that the current data regarding reprocessing of single use devices raises potentially serious safety and effectiveness concerns is inexplicable.

To date, FDA has failed to make public any study reports summarizing OST's data. Nonetheless, public presentations by OST scientists clearly indicate that these findings include safety and effectiveness concerns with percutaneous transluminal coronary angioplasty (PTCA) catheters, electrophysiology catheters, and biopsy forceps.[33] One presentation revealed PTCA catheters with non-patent lumens, crimped guidewires, and

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31 See Warning Letter from Douglas Tolen, Director, Florida District Office, FDA. to Charles Masek, Jr., President & CEO, Vanguard Medical Concepts, Inc., at 2 (Oct. 14, 1999).

32 See Statement of Donald Marlowe, Director, OST, CDRH, FDA, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel I) (Nov. 10, 1999) ("Our own data was developed in-house, specifically to help us begin to understand the areas of concern. . . . None of this was intended to be exhaustive.").

33 See Transcript of May 5-6, 1999 FDA/Association for the Advancement of Medical Instrumentation (AAMI) Conference on the Reuse of Single-Use Devices at 66 (statement of Katherine Merritt, Ph.D., Research Biologist, Division of Life Science and Technology, OST, CDRH, FDA) ("In terms of the PCTA catheters, we know we have many models. Not all of them behave the same . . . . Some guidewire lumens kink easily. Some get clogged and some leak.").

plugged balloons or balloon channels. In some instances, cleaning chemicals and blood could not be removed from the device lumens. Some reprocessed PTCA balloons varied in size by more than 10% of the approved specifications. The result of such variation is a lack of certainty in whether a cardiologist will actually utilize the particular balloon size originally intended for the patient.

3. Published literature

FDA has generally based a decision that a device is safe on prospective controlled studies rather than on published literature reports. With respect to single use device reprocessing, however, FDA has repeatedly referenced specific "researchers" and "publications" that purport to have demonstrated the safety of reprocessing. There is no justification for FDA to rely on published literature as a substitute for premarket submissions. In addition, ADDM has serious concerns with the science supporting the cited literature. A stakeholder at FDA's December 1999 Stakeholder Meeting noted that these particular studies would not be accepted under traditional peer review standards.[34]

While citing articles that reportedly found no safety problems, FDA has not recognized published literature demonstrating the risk of reuse of disposable devices. The agency has disregarded at least three published scientific reports that confirm the physical, microbiological, and functional performance failures that are associated with reprocessed single use devices.

One article draws a correlation between the increased incidence of pneumonia in pediatric patients and the reuse of tracheostomy tubes, which are devices labeled as "single use only." Tracheostomy tube reuse was reported by 55% of the sixty participants. Approximately 60% of the pediatric patients on whom reprocessed tracheostomy tubes were used developed pneumonia within the previous year, compared to only 25% of pediatric patients on whom new tracheostomy tubes were used in the same time period.

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[34] See Transcript of Dec. 14, 1999 FDA Public Meeting: FDA's Proposed Strategy on Reuse of Single Use Devices at 57 (statement of Janet Schultz, RN, MSN, Jan Schultz & Assoc.) ("[T]here have been some studies in the medical literature purporting to demonstrate the safety of reuse. On closer examination, few, if any, of these would pass scientific peer review in the areas of microbiologic or epidemiologic methods. And for those that claim to be patient outcome studies, few have adhered to even the most basic FDA requirements for research on human subjects when it comes to informed consent.").

Other potential variables, such as patient age, diagnosis, method of tube cleaning, and frequency of tube change showed no correlation to increased incidence of pneumonia. Tracheostomy tube reuse was the only predictor of pneumonia and thus it is not surprising that the authors' conclusion questions the safety of reusing these single use devices.[35]

Another article reports that a 57 year-old man experienced a sudden loss of vision in one eye during a cardiac catheterization for coronary angiography after a heart attack. The loss of vision was due to a reprocessed catheter, the tip of which fragmented and lodged in the central retinal artery on the optic nerve head of the patient's right eye, leaving that eye with only light perception vision. At the end of a six-month follow-up, the patient's right eye vision remained limited to perception and nasal projection of light. The catheter fragmentation was attributed to the reautoclaving process and the reuse of the single use device. The authors recommend compliance with manufacturers' single use label to prevent this type of complication.[36]

A third article highlights a very important public health issue associated with reprocessing single use devices: *antibiotic resistance*. The report reveals that reprocessed stopcocks labeled "single use only" led to a pseudo-outbreak in which nine patients were misdiagnosed as being infected with *Aureobasidium*, a genus of the fungus known as "black yeast." Had this erroneous diagnosis involved a bacterial organism, these patients would have likely received unnecessary antibiotic treatment for their "infections." This article demonstrates that reprocessed single use devices have the potential to be serious contributors to the growing problem of antibiotic resistance in the United States.[37]

Because these articles, like those cited by FDA and the reprocessing industry, point to safety issues associated with particular types of devices, they can not be used as a basis

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35 Susanne C. Bahng, et al., Parental Report of Pediatric Tracheostomy Care, 79 Arch Phys Med. Rehabil. 1367 (1998).

36 Dietrich Hallerman, M.D. and Guridner Singh, M.D, Iatrogenic Central Retinal Artery Embolization: A Complication of Cardiac Catheterization, 16 Annals of Opthamology 1025 (Nov. 1984).

37 Stephen J. Wilson, et al., A Pseudo-Outbreak of *Aureobasidium* Lower Respiratory Tract Infections Caused by Reuse of 'Single Use' Stopcocks During Bronchoscopy, Infections Disease Society of America (IDSA) Conference (Nov. 18-21, 1999) (This abstract was included in materials distributed at the IDSA Conference).

for generalized statements regarding the safety of reprocessing all devices. At most. particular studies can speak to the safety of the specific model of device reprocessed.[38] Only device-specific, model-by-model data can demonstrate whether a particular single use device, reprocessed by a particular entity, is likely to be safe. Such data must be submitted to, and cleared or approved by, FDA in a 510(k) or PMA before the safety and effectiveness of a reprocessed single use device is truly known.

4. MedWatch reports

While, FDA has acknowledged that reports in its MDR database suggest that problems may exist with reprocessed single use devices, it has discounted such reports because, in FDA's opinion, the device failure often cannot be definitively linked to the reprocessing.[39] Others have suggested that if a reused single use device fails by a failure mode that has also occurred with new devices, then that failure should not be attributed to the reprocessing. This is an unjustified conclusion. If the device is being used a second, third or sixth time. the device must have functioned properly the first time –as intended. If the device had been used once and discarded, in accordance with its labeling. it would not have failed. Exhaustion of the device's safety margins by reprocessing will cause the device to fail, perhaps by a failure mode that has also occurred with new devices. This overlap in failure modes does not absolve the reprocessor from responsibility for the device's failure and certainly does not substantiate claims that reprocessing is safe.

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38 Transcript of May 5-6, 1999 FDA/AAMI Conference on the Reuse of Single-Use Devices at 77 (statement of Richard Kozarek, M.D., Chief of Gastroenterology, Virginia Mason Medical Center and Clinical Professor of Medicine, University of Washington at Seattle) ("I can't say that [another OEM's] devices could be reprocessed the same way. I can't comment on triple lumened sphincterotomes when I studied double and single lumened sphincterotomes. . . .").

39 See Statement of Larry Kessler Sc.D., Director, Office of Surveillance and Biometrics (OSB), CDRH, FDA, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel I) (Nov. 10, 1999) ("Some reports we have in that system suggest some problems associated with products that might have been reprocessed; so we might see cracking of some catheters, but I need to remind people who look to that system that its an excellent system for signaling potential problems, but it's not great for cause and effect. It's not the same as systematic science to prove a problem. So we have some suggestions of some problems but they're limited and it's not clear or documented scientific evidence that we can count on.").

FDA's willingness to disregard MDR reports that it deems not unquestionably linked to reprocessing is also inconsistent with the agency's traditional use of the MDR database. FDA has previously used MDR reports as evidence that a problem exists and needs to be addressed. This is true even if the causal relationship is tenuous. as in cases of device misuse. For example, if a practitioner uses a medical device in a way that was clearly not intended and reports a device failure, that failure is attributable to the manufacturer. Nonetheless, under FDA's current thinking, it appears that failures associated with reprocessed single use devices must be *definitively* linked to the reprocessing for FDA to consider them as an indication of the risk of reprocessing.

Despite its admonitions that reports in the MDR database do not definitively demonstrate patient risk for reprocessed disposable devices, FDA has allowed the converse inference to be drawn – that the database *does* demonstrate a *lack of* patient risk. At FDA's November 1999 videoconference, FDA failed to correct a panelist's statements that this database amounts to a "staggeringly extraordinary safety record."[40] It is telling that twice during that same panelist's comments he stated that when a reprocessed device fails during use he throws it away –never filing an MDR report.[41] The apparent safety record of reprocessing will continue to be characterized as "extraordinary" if device failures are not reported.

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[40] See Statements of Douglas B. Nelson, M.D., gastroenterologist, Veterans Affairs Medical Center, Minneapolis, MN and Assistant Professor of Medicine. University of Minneapolis, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel III) (Nov. 10, 1999) ("Twenty years of MDR reporting or fifteen years of MDR reporting -again, FDA's own statement that FDA has been unable to find clear evidence of adverse patient outcome associated with the reuse of single use devices from any source. To put that into perspective, fifteen to twenty years of doing procedures approximately ten million procedures per year without adverse events. That is a staggeringly extraordinary safety record.").

[41] See id. (Dr. Nelson made the following two statements: "If I put a device through my endoscope and it looked great but happened to go down there and failed, what is the down side to that? I pull it out and throw it away," and "What happens to a GI device if it fails? If I put this small instrument into my endoscope and it comes out and doesn't work, I have to pull it out and throw it away. That costs about ten seconds.").

FDA has failed to recognize the demonstrated patient safety risks associated with reprocessing single use devices despite the volumes of data to the contrary. Reprocessing amounts to a misuse of medical devices that can only add to the nation's preventable medical error rate. The agency's congressional mandate to protect the public will not be served by reversing the burden of proof and awaiting a proven public health disaster before taking action.

D. FDA has a Long History of Unclear and Inconsistent Policies Regarding Single Use Device Reprocessing

The history of FDA's policy regarding reprocessed single use devices is marked with inconsistency. From FDA's public acknowledgment of the safety hazards posed by reprocessing single use devices in 1987 to the 1999 publication of the FDA Proposed Strategy recommending continued FDA inaction for many devices, the agency has failed to articulate a coherent policy or analytical framework. The solution to this tortured regulatory construct is simple: full enforcement of the FDC Act, including all device regulations and premarket submission requirements, on reprocessors of single use devices. Such enforcement would result in a clear and coherent policy that can be applied equitably to reprocessors and OEMs and will ensure patient safety.

1. Compliance Policy Guide (CPG) 300.500

In 1987, FDA revised section 300.500, "Reuse of Medical Disposable Devices," of CPG 7124.16. In the CPG, FDA concluded that "[t]he reuse of disposable devices represents a practice which could affect both the safety and effectiveness of the device."[42] FDA made this assertion based on a lack of data "establish[ing] conditions for the safe and effective cleaning and subsequent resterilization and/or reuse of any disposable medical devices."[43] At that time, FDA appropriately recognized that such a lack of data should result in a "single use label" for patient protection. FDA further recognized that to establish the safety and effectiveness of a single use device, a reprocessed device must demonstrate all three of the following criteria:

(1) that the device can be adequately cleaned and sterilized;

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[42] FDA Compliance Policy Guide 7124.16, § 300.500, "Reuse of Medical Disposable Devices" (1987).

[43] Id.

(2) that the physical characteristics or quality of the device will not be adversely affected by such processing; and

(3) that the device remains safe and effective for its intended use after such reprocessing.[44]

While the CPG appropriately recognized these three key criteria for ensuring patient safety, it inappropriately placed the burden for demonstrating safety and effectiveness on the user rather than the reprocessor. In fact, under the CPG, the reprocessor has no regulatory obligation whatsoever –not even compliance with the QSR or registration and listing requirements. The CPG also fails to place any obligation on FDA to review data and clear or approve these devices. Had the onus been appropriately placed on reprocessors and FDA to ensure that the elements of the CPG were met, patients would have been protected from unsafe and ineffective reprocessed single use devices for the past thirteen years.

2. FDA letter to manufacturers and facilities

In a December 27, 1995 letter from FDA to the American College of Healthcare Executives, the agency attempted to clarify its policy on single use devices. FDA stated.

> [C]onsistent with existing regulations, any person or firm that reprocesses medical devices for health care facilities and engages in repackage [sic.] relabeling, or sterilization operations (including any associated processing activities; e.g., cleaning), are [sic.] required to comply with the Good Manufacturing Practice (GMP) and device labeling requirements of the Federal regulations.[45]

The letter, however, failed to state that 510(k)s are required for such reprocessing, but instead noted that "FDA is evaluating those situations in which submission of a 510(k) or PMA supplement would be required for reprocessing of devices."[46] Had FDA announced, in 1995, that all reprocessors of single use devices must obtain premarket

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[44] Id.

[45] Letter from Lillian Gill, Director, OC, CDRH, FDA, to the American College of Healthcare Executives, at 1 (Dec. 27, 1995).

[46] Id.

clearance or approval, patients would have been afforded the protection they are due under the FDC Act.

3. FDA response to the Health Industry Manufacturers Association (HIMA) citizen petition

In September 1997, HIMA filed a citizen petition seeking to clarify FDA's regulatory position with respect to premarket submissions for reprocessed single use devices.[47] In a July 13, 1998 response to that petition, the agency restated its position in the December 27, 1995 letter that reprocessors of single use devices must adhere to medical device Good Manufacturing Practices (GMPs)/QSR and labeling regulations. The letter further stated that reprocessors are subject to MDR requirements, and that based on MDR data, there is a "general absence of evidence of adverse patient outcomes attributed to the reuse of single-use devices."[48] Based on the apparent assumption that a lack of MDR reports confirms safety, the agency concluded that there is a reasonable assurance that reprocessed single use devices meet the "appropriate specifications for safety and performance,"[49] and stated that "compliance with GMP requirements provides an appropriate measure of public health protection for patients and health care providers by ensuring sufficient control over the individual firm's manufacturing and quality assurance operations."[50]

FDA's refusal to enforce the premarket requirements because of a supposed lack of evidence of harm stands the FDC Act on its head. It is the obligation of the party that wishes to market the device –in this case the reprocessor– to show that the device is safe and effective.[51] FDA's reliance on a lack of MDR reports is inconsistent with the agency's

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47 See HIMA Citizen Petition to FDA Dockets Management Branch, at 1-2 (FDA Docket No. 97P-0377) (Sept. 5, 1997) (requesting FDA to apply "all applicable FDA regulations governing medical device manufacturing" to commercial reprocessors of disposable medical devices).

48 Letter from Bruce Burlington, M.D., Director, CDRH, FDA, to Nancy Singer, Esq., Special Counsel, HIMA, at 2 (July 15, 1998) (FDA Docket No. 97P-0377).

49 Id.

50 Id.

51 See supra note 23.

typical interpretation of the evidence in that database. This is especially inappropriate in light of the unique factors surrounding reprocessed single use devices. Physicians often incorrectly report device failures of reprocessed devices to the OEM, or simply fail to report reprocessed device failures at all.[52]

4. FDA letters to AMDR

In a later-rescinded October 19, 1998 letter to the Association of Medical Device Reprocessors (AMDR), FDA stated "[t]hird-party reprocessing of devices labeled for single use is lawful in the United States provided that the reprocessing firm complies fully with all regulatory requirements currently imposed on them. The most significant regulatory requirement, at this time, is compliance with the newly developed Quality System regulation."[53] The letter made no mention of premarket submission requirements. Based on this letter and FDA's response to the HIMA citizen petition, reprocessors began to assert in their marketing materials and elsewhere that FDA considered reprocessed single use devices to be safe and lawful.[54]

Nine months later, the agency finally corrected its statements. In a July 9. 1999 letter to AMDR, the agency rescinded the statement quoted above and replaced it with the following statement: "Third-party reprocessing of devices labeled for single use is *unlawful* unless those engaged in the this practice comply with *all* regulatory requirements for manufacturers, *including premarket notification requirements*."[55] Although this statement

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52 During FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Nov. 10, 1999), one panel member/physician commented that if a reprocessed single use device fails during a procedure, he simply discards of the device. He made no mention of filing an MDR. See supra note 41.

53 Letter from Larry Spears, Director, Division of Enforcement III, OC, CDRH, FDA, to Stephen Terman, Esq., Olsson, Frank and Weeda, P.C. (Oct. 19, 1998).

54 See Letter from Josephine Torrente, Esq., Hyman, Phelps & McNamara PC, to Lillian Gill, Director, OC, CDRH, FDA (Feb. 4, 1999) (alerting FDA to reprocessors' use of published articles to distort the agency's position regarding reprocessing single use devices).

55 Letter from Larry Spears, Director, Division of Enforcement III, OC, CDRH, FDA, to Stephen Terman, Esq., Olsson, Frank and Weeda, P.C. (July 9, 1999) (emphasis added).

accurately represents the correct regulatory status of reprocessed single use devices. FDA again announced its intention to ignore violations of the premarket requirements.

5. FDA Response to Medical Device Manufacturers Association (MDMA) citizen petition

On May 20, 1999, the MDMA submitted a citizen petition to FDA requesting that the agency ban the practice of reprocessing single use devices.[56] On October 6, 1999, FDA denied MDMA's petition citing a lack of "evidence that reprocessing presents 'an unreasonable and substantial risk of illness or injury.'"[57] FDA's explanation for denying the petition was unduly brief and failed to address the content of the petition. Further, while FDA acknowledged receipt of adverse event reports related to reprocessed single use devices, the agency did not specifically reference any of the information it has in its possession. It was the responsibility of the agency to provide a more thorough explanation for why it denied the petition. This response prompted MDMA to resubmit the citizen petition and request that FDA place all relevant materials in the docket.[58]

6. Other guidance documents and letters

In addition to the documents discussed above, several other recent agency pronouncements point to FDA's inconsistent approach to the regulation of single use device reprocessing and demonstrate the agency's unwillingness to recognize the seriousness of the issue.

a. FDA/CDC Endoscope Guidance

In a September 10, 1999 FDA and Centers for Disease Control and Prevention (CDC) public health advisory entitled "Infections from Endoscopes Inadequately Reprocessed by an Automated Endoscope Reprocessing System," FDA recommends that to

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[56] See MDMA Citizen Petition to FDA Dockets Management Branch (FDA Docket No. 99P-1516) (May 20, 1999).

[57] Letter from David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA, to Larry Pilot, Esq., McKenna & Cuneo, L.L.P. (counsel for MDMA), at 1 (Oct. 6, 1999) (FDA Docket No. 99P-1516) (quoting one criterion for banning a medical device).

[58] Letter from Larry Pilot, Esq., McKenna & Cuneo, L.L.P., to David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA (FDA Docket No. 99P-1516) (October 21, 1999).

avoid contamination of *reusable* endoscopes, health care facilities should, "[b]e sure that all staff who handle soiled endoscopes *comply with the endoscope manufacturer's instructions for cleaning* the endoscope."[59] It is curious that in the case of a reusable device, such as an endoscope, the agency recommends that reprocessing should be done only in accordance with an OEM's instructions since the device manufacturer best understands the device's ability to be reprocessed; yet, in the case of single use devices, FDA allows the OEM's instructions to be ignored. Devices marketed as "single use only" are designed and manufactured for one patient use only. In fact, without data demonstrating the safety and effectiveness of a device for multiple use, FDA requires a single use label. Since FDA recommends that healthcare facilities which reprocess endoscopes follow the OEM's instructions, the agency should also advise healthcare facilities to defer to an OEM's instructions on single use devices.

b. Human Dura Mater Guidance

On October 14, 1999, FDA issued a guidance document entitled, "Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater." In that document, FDA, acknowledging the contamination issues associated with reprocessing certain devices, states that human dura mater "procedures should require the use of only disposable . . . surgical instruments[,] . . . [b]ecause FDA is unaware of any procedure or reagent that is validated to totally inactivate the CJD-causing agent . . . ."[60] FDA's position recognizes that a substantial risk of cross-contamination is associated with reprocessing devices that are used in human dura mater grafts. These devices, however, are the same as, or similar to, devices used for other invasive procedures which FDA permits to be reprocessed and used in multiple patients without any premarket showing of safety and effectiveness.

According to the human dura mater guidance document, the use of reprocessed devices must be justified to FDA *prior to implementation*.[61] Similarly, because of the risks to which patients are exposed when reprocessed single use devices are used during many

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59 FDA and CDC, Public Health Advisory, Infections from Endoscopes Inadequately Reprocessed by an Automated Endoscope Reprocessing System, at 2 (Sept. 10, 1999) (emphasis added).

60 Guidance for the Preparation of a Premarket Notification Application for Processed Human Dura Mater, CDRH, FDA, at 7 (Oct. 14, 1999).

61 Id. (emphasis added).

other procedures, reprocessors should be required to demonstrate through a premarket submission that the device is safe and effective for its intended use prior to implementation. FDA – consistent with its historical practice – did not, in this instance, wait for evidence of patient injury or death before acting.

c. The Electrode Store and Breath of Life Warning Letters

As stated above, a change from single use to multiple use is a significant change in the intended use of a device that could significantly affect the safety and/or effectiveness of a device, and therefore, requires a 510(k) or PMA regardless of whether this change is implemented by the OEM or the reprocessor. In warning letters and other guidance documents issued to OEMs, FDA has consistently held that "[i]n order to market a single use device as reusable, a new 510(k) is required since there is a potential impact on the safety and effectiveness of the device."[62] For example, in a May 9, 1997 warning letter to Breath of Life, FDA cited the manufacturer for failure to submit a 510(k) for a change from single use to reusable because of a kit that was distributed with its emergency manual resuscitator. FDA claimed that the kit effectively changed the intended use of the device from single use to multiple use and thus necessitated a 510(k) clearance.[63] In a similar warning letter issued to The Electrode Store on June 21, 1999, FDA, using the same reasoning as in its warning letter to Breath of Life, stated that "[w]ith regard to the reusable monopolar and concentric needle electrodes . . . [marketed by The Electrode Store], CDRH has determined that a 510(k) is necessary *because the indications have been changed from single use to multiple use.*"[64]

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62 Questions and Answers for the FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities, CDRH, FDA, at 6 (Sept. 3, 1996). This statement was made in response to the following question: "I have a device which is cleared for single use. If I want to market it as reusable what is required?" Id.

63 Warning Letter from Lillian Gill, Director, OC, CDRH, FDA, to Robert Chester, Breath of Life, at 2 (May 9, 1997).

64 Warning Letter from Roger Lowell, District Director, Seattle District Office, FDA, to Timothy Cooke, President, The Electrode Store, Inc., at 2 (June 21, 1999) (emphasis added).

d. Third-Party Reprocessor Warning Letters

In the past six months, FDA has issued at least three warning letters to reprocessors. The deficiencies evidenced in these letters reveal violative practices in an industry that is not required to prove its claims before subjecting patients to its devices. For instance, in an October 14, 1999 warning letter sent to a major reprocessor, FDA noted a failure to appropriately validate the sterilization process, a lack of recorded data on various processes, and incomplete sterilization of devices.[65] In a December 23, 1999 warning letter to another major reprocessor, FDA reported findings of inadequately trained personnel who were unaware of FDA's QSR, in addition to incomplete or missing records on facility and equipment maintenance and cleaning.[66] Similarly, in a January 6, 2000 warning letter to a reprocessing company, FDA notes that devices resterilized with ethylene oxide (EtO) are not adequately tested for EtO residues, tensile strength or other degradation.[67] If premarket submission requirements had been enforced, the greater FDA oversight may have prevented these violations from occurring.

In at least one situation, FDA's actions provided too little protection for a particular patient. An April 1998 warning letter to a major third party reprocessor noted, among other things, that the reprocessor failed to establish the maximum number of reprocessing cycles

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[65] See Warning Letter from Douglas Tolen, Director, Florida District Office, FDA, to Charles Masek, Jr., President and CEO, Vanguard Medical Concepts, Inc. (Oct. 14, 1999).

[66] See Warning Letter from Douglas Tolen, Director, Florida District Office, FDA, to Rick Ferreira, CEO, Alliance Medical Corp. (Dec. 23, 1999) (noting Alliance Medical Corporation's "[f]ailure to establish and implement a quality policy [,] . . . . [f]ailure to establish and maintain procedures to ensure that device history records are maintained [,] . . . .[f]ailure to establish and maintain procedures for implementing corrective and preventive action [,] . . . .[f]ailure to monitor production and process controls to ensure that inspection, measuring, and test equipment is suitable and capable of performing its intended purpose [,] . . . .[f]ailure to adequately train personnel to perform their assigned responsibilities [, and] . . . .[f]ailure to document cleaning and maintenance of the facility and process equipment . . . .").

[67] See Warning Letter from Edward R. Atkins, Acting Director, Florida District Office, FDA, to Louis L. Rudt, President, Visions in Endosurgery, Inc. (Jan. 6, 2000).

that electrophysiology catheters could withstand.[68] Less than one year later, an electrophysiology catheter that had been reprocessed five times by that company failed catastrophically while being used on a patient. A portion of the catheter's metal electrode became lodged in the right atrium of the patient's heart.

As is evident from these documents and others like them, FDA's position on the safety of reprocessed single use devices and the degree of regulatory control necessary to achieve acceptable levels of safety has vacillated. In the eighteen months since FDA denied the HIMA citizen petition, FDA has (1) implied that reprocessing single use devices is safe, (2) noted that devices should not be reprocessed except in accordance with the OEM's instructions, (3) required prior justification for reuse of surgical instruments in certain procedures, (4) noted that a change from single use to reusable could affect safety and effectiveness and therefore requires a 510(k) clearance, (5) failed to require 510(k)s from reprocessors by stating that compliance with the QSR was sufficient to ensure patient safety, (6) cited reprocessors for multiple QSR violations, (7) relied on a lack of substantial numbers of MDR reports to claim that reprocessing single use devices is safe, and (8) demanded corrective action by OEMs based on isolated events. FDA's incoherent policy can be easily fixed by applying the FDC Act to reprocessors of single use devices.

E. The FDA Proposed Strategy Further Delays Appropriate Regulation of Reprocessing

FDA has had numerous opportunities to address the issue of reprocessed single use devices by fully enforcing the FDC Act, including the requirements for premarket submissions. A myriad of meetings and proposals, however, has delayed reprocessors' compliance with the law. The latest such proposal is the FDA Proposed Strategy. The FDA Proposed Strategy provides no substantive resolution to this issue despite more than four years of ongoing debate. The agency must abandon the FDA Proposed Strategy and instead enforce the FDC Act, including the requirements for premarket submissions.

The May 1999 FDA/AAMI meeting provided ample opportunity to address the issue of reprocessing single use devices and demonstrated the need for immediate FDA action. At the meeting, numerous presenters, including practicing physicians, expressed concern about the safety of reprocessing single use devices and requested that FDA take action.

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[68] See Warning Letter from Ballard H. Graham, Director, Atlanta District Office, FDA, to William T. Stover, Chairman and Chief Executive Officer, Paragon Healthcare Corporation (April 14, 1998).

Despite its consideration of the issue, however, FDA seemed unwilling to act. For example, one FDA official noted that "what FDA needs to do is help take the leadership role in creating a shared vision for what the manufacturing and reprocessing systems should look like *in five and ten years*."[69] Another FDA official commented that "there will be ample opportunity for *multiple* comments on [this] plan."[70] Other officials noted that developing and implementing a policy on reuse would take tremendous time and effort and would strain agency resources.[71] Despite the purported lack of resources to address the problem in the United States, however, one FDA official suggested that FDA should expand discussion on the issue to a global audience.[72]

Six months after the meeting, FDA published the "FDA Proposed Strategy." This is a misnomer since it is not truly a strategy at all. Rather, it appears to be a list of things the agency would like to take into account in developing a strategy. In lieu of setting requirements, the FDA Proposed Strategy uses terms such as "explore," "examine," and "consider." The effort spent on exploring, examining, and considering alternatives to what current law already demands from reprocessors should instead be spent enforcing that law.

Furthermore, the FDA Proposed Strategy lacks sufficient detail to allow meaningful comment. One startling example is section four which says, "consider requesting OEMs to

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69 Transcript of May 5-6, 1999 FDA/AAMI Conference on the Reuse of Single-Use Devices at 253 (statement of Larry Kessler, Sc.D., Director, OSB, CDRH, FDA) (emphasis added).

70 Id. at 6 (statement of Elizabeth Jacobson, Acting Director, CDRH, FDA) (emphasis added).

71 In reference to developing a new regulatory framework for reprocessed single-use devices, one FDA official said, "it requires a lot of time and effort to work up a new program, a new issue like this, and any way you cut it, it's going to mean time and effort." Id. at 224 (statement of Timothy Ulatowski, M.S., Director, Division of Dental Infection Control and General Hospital Devices (DDIGD), ODE, CDRH, FDA).

72 An FDA official stated, "this isn't just the US FDA perspective . . . . this is a worldwide . . . global concern. I do think that we've got to expand the discussion on this." Id. at 233-234 (statement of Lillian Gill, Director, OC, CDRH, FDA).

provide information on their labels about risks associated with the reuse of SUDs."[73] This section, which proposes to significantly reinterpret the FDC Act's device labeling provision, and place a significant burden on OEMs, is described in a mere eight lines, four of which explain current law. The FDA Proposed Strategy continues, "[o]ne option the [a]gency is considering . . .,"[74] but fails to adequately explain the option and does not mention any alternatives. A strategy that proposes to significantly re-write the FDC Act certainly deserves more explanation than this.

In addition to lacking adequate explanation, the FDA Proposed Strategy does not include a deadline for the submission of comments. Without a firm comment deadline, a quick resolution of this important public safety issue is unlikely. The lack of a comment deadline may also force the agency to delay publishing a final document as new comments continue to be submitted to the docket. On December 9, 1999, FDA released the Risk Categorization Guidance on the internet. This document is intended to complement the FDA Proposed Strategy. Although this second guidance document *does* establish a comment deadline of ninety days post-publication in the Federal Register, to date, FDA has failed to formally publish the Risk Categorization Guidance.

At FDA's December 1999 Stakeholder Meeting on the FDA Proposed Strategy, the agency proposed several measures that largely duplicate the guidances and policies that already exist for reusable devices. These include the development of guidance on sterility validation, the development of guidance on registration and listing, the development of auditing programs, the development of regulation on labeling, and the development of horizontal and vertical standards. All of these duplicative actions would take significant time to draft, complete, and implement. Meanwhile, patients would be left unprotected from the risks associated with using reprocessed single use devices.

Despite its prolonged gestation period, the FDA Proposed Strategy fails to conform to the Food and Drug Administration Modernization Act of 1997's (FDAMA's) provision and FDA's own regulations governing guidance documents. Section 405 of FDAMA guarantees that "[t]he Secretary shall ensure uniform nomenclature for [informal agency statements, and] . . . that guidance documents . . . indicate the nonbinding nature of the documents."[75] The FDA Proposed Strategy is not even identified as a guidance document,

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73 FDA Proposed Strategy at 13.

74 Id.

75 See Pub. L. No. 105-115, 111 Stat. 2296 (1997) § 405.

an advanced notice of proposed rulemaking or any other recognizable regulatory publication. This oversight has led FDA to coin a neologism to identify the FDA Proposed Strategy: "an advanced notice of a proposed guidance with options."[76] FDA must abandon this approach and publish the direct to final rule set forth in the ADDM Strategy.[77] That rule establishes staggered temporary exemptions from premarket submission requirements for reprocessed Class I and Class II single use devices, and sets deadlines for submissions for all reprocessed single use devices.

F. The FDA Proposed Strategy Confuses Issues Surrounding Reprocessing

The FDA Proposed Strategy introduces ancillary concepts to the current controversy surrounding the reprocessing of single use devices, and uses imprecise and incorrect terminology causing confusion over the issue. The inconsistencies set out in this section further illustrate why the FDA Proposed Strategy is fundamentally flawed.

1. Inclusion of opened but unused devices

The FDA Proposed Strategy unnecessarily refers to opened but unused single use devices. Because these have not been exposed to patients and because they are not subjected to harsh cleaning techniques, they pose different safety risks than do reprocessed used single use devices. FDA, at the May 1999 FDA/AAMI meeting on reuse, recognized this difference and considered opened but unused devices to be outside the scope of that meeting. Incorporating opened but unused devices into the FDA Proposed Strategy only confuses and complicates the discussion of patient safety issues. FDA's second guidance document on reprocessed single use devices, issued only one month after the FDA Proposed Strategy, properly excludes open but unused devices.

The FDA Proposed Strategy suggests a working definition of "single use devices" that appears to include both used and unused disposable devices, and refers throughout to regulation of "single use devices," thereby including both. FDA's suggested working definition of single use devices blurs the distinction between used single use devices and opened but unused single use devices, and, in turn, confuses the focus of the FDA Proposed Strategy. FDA's resources would be better used, and the public health better served, by

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[76] Karen Riley, FDA discloses reuse plans as political pressure grows, Clinica: World Medical Device & Diagnostic News, Oct. 11, 1999, at 1.

[77] See supra note 5.

ensuring that reprocessors of *used* single use devices comply with the FDC Act. FDA should continue to recommend that open and unused devices should only be resterilized in accordance with directions provided by the OEM. If the OEM provides no directions for a particular product, then that device should not be resterilized.

2. "Reuse" vs. "reprocessing"

The very title of the FDA Proposed Strategy, "FDA's Proposed Strategy on the Reuse of Single Use Medical Devices," confuses regulation of the medical practice of reuse with the manufacturing activity of reprocessing. FDA has the authority to regulate only the latter. The purpose of the FDA Proposed Strategy should be to design a regulatory framework to ensure that the *manufacturing activity of reprocessing* single use devices does not jeopardize patient health. It should not establish a regulatory framework for the *medical practice of reuse* of single use devices. FDA's own proposed working definitions of "reuse" and "reprocessing" suggest that there is a significant difference between the two terms.[78] While the definition section of the FDA Proposed Strategy acknowledges this distinction, the remainder of the FDA Proposed Strategy often uses the two terms interchangeably. Once again, this illustrates the analytical carelessness pervading the document.

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[78] The FDA Proposed Strategy suggests the following definitions for the terms "reuse" and "reprocessing:"

> **Reuse:** the repeated use or multiple uses of any medical device, including reusable and single-use medical devices, on the same patient or on different patients, with applicable reprocessing (cleaning and disinfection/sterilization) between uses.
>
> **Reprocessing:** includes all operations performed to render a contaminated reusable or single-use device patient-ready or to allow an unused product that has been opened to be made patient-ready. The steps may include cleaning and disinfection/sterilization. The manufacturer of reusable devices and single use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labeling.

FDA Proposed Strategy at 14 (reformatted for convenience).

3. Regulation of "low" risk devices

In addition to the inconsistent treatment of opened but unused devices. the FDA Proposed Strategy and the agency's interpretation of the Risk Categorization Guidance are at odds with respect to how devices characterized as "low" risk will be regulated. The FDA Proposed Strategy specifically notes that "FDA plans to exercise enforcement discretion not to enforce 510(k) submission requirements" for devices deemed to be "low" risk.[79] Nonetheless, at FDA's December 1999 Stakeholder Meeting on this issue, an FDA official characterized the risk categorization scheme as "a scheme to *prioritize* submissions of premarket applications . . . a way to prioritize the receipt and review of these applications,"[80] implying that even "low" risk devices would be required to be cleared or approved by FDA. When questioned about the discrepancy, FDA was unable to reconcile the two statements or to tell which is correct.[81]

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79 Id. at 10-11.

80 Transcript of Dec. 14, 1999 FDA Public Meeting: Reuse of Single Use Devices-FDA Proposed Strategy at 134-35 (statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA) (emphasis added).

81 One FDA official stated that "[FDA's] intention, our major intention here in terms of public health[,] is to get what we think are the most significant devices that are reused looked at very quickly and to pause with the others to allow for data collection and let the scheme play a little bit in regard to mitigation of risk, perhaps with data collection." Id. at 178 (statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA).

4. Creation of the term "SUD"

The FDA Proposed Strategy substitutes the term "SUDs" for single use devices. Reference to single use devices as "SUDs" incorrectly implies that these are a homogenous group of devices capable of being regulated as a set. In fact, devices designed and labeled for single use only may be (1) made from a variety of materials including metals, ceramics, and various plastics, (2) intended to be used in or on various parts of the body including the heart, the gastrointestinal tract or the intact skin, (3) designed to include long lumens, flat surfaces, coiled wires or delicate interfaces, and (4) categorized into Class I, II or III based on their risk level. FDA's reference to these devices as "SUDs" creates the false impression that, once reprocessed, they can be standardized and regulated as a group when, in fact, each model of each device type must be regulated individually. FDA should abandon using the acronym "SUD" which implies a false level of uniformity.

G. FDA's Exercise of Enforcement Discretion Raises Significant Medicare Reimbursement Issues

The agency's position to date, which allows unlawfully reprocessed devices to be used in hospitals, has created reimbursement issues. The Health Care Financing Administration (HCFA) will allow reimbursement for reprocessed medical devices only if such reprocessing is otherwise lawful. In a letter dated September 8, 1999, HCFA clarified that, "[i]f FDA's current position is that reprocessing of single-use medical devices is unlawful absent premarket notification, these devices will not be covered under Medicare."[82] The agency's statements to date, and the FDA Proposed Strategy, have put hospitals in an untenable position with respect to Medicare. The scenario created by FDA's actions is perpetuated by the FDA Proposed Strategy causing potentially significant reimbursement concerns for many health care providers.

The Medicare reimbursement issues can be easily resolved: FDA must discontinue its use of enforcement discretion and ensure that any reprocessed disposable devices used in hospitals are reprocessed in accordance with the FDC Act. The FDA Proposed Strategy fails to achieve this goal. In fact, devices characterized as "low" risk or "moderate" risk under the Risk Categorization Guidance would continue to be reprocessed unlawfully leaving both HCFA and hospitals in regulatory limbo.

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[82] Letter from Grant Bagley, M.D., Director, Coverage and Analysis Group, HCFA, to Josephine Torrente, Esq., Hyman, Phelps & McNamara, P.C. (Sept. 8, 1999).

The FDA Proposed Strategy precludes hospitals from obtaining *any* Medicare reimbursement for reprocessed single use devices. While it has always been apparent that healthcare facilities cannot recoup the full cost of a new device when a less expensive reprocessed device is used, the September 8, 1999 HCFA letter makes clear that even the cost of the reprocessed device is not reimbursable if the device is reprocessed without a 510(k) or PMA because the reprocessing itself is unlawful. Unlike the FDA Proposed Strategy, the ADDM Strategy resolves these Medicare issues by ensuring that all reprocessed devices are lawfully marketed.[83]

H. FDA Must Utilize its Resources to Enforce the FDC Act

FDA has repeatedly defended its lack of action against reprocessed single use devices on the basis of limited resources. However, FDA has proposed a strategy that squanders resources while never definitively making safety and effectiveness determinations for most devices. The FDA Proposed Strategy requires development of consensus standards, administration of outreach programs, and enlargement of OST research efforts. While each of these initiatives may be laudable for an agency with limitless funds, none is a substitute for the core statutory requirement of premarket review. In addition, the need for these initiatives would be largely obviated by FDA's determinations of device safety and effectiveness in connection with premarket submissions.

In justifying its claim of inadequate resources, FDA has erroneously hypothesized that thousands of hospitals and reprocessors would each submit thousands of 510(k)s simultaneously if FDA were to enforce the law. FDA is aware, however, that due to several factors, only a very limited number of premarket submissions are likely to be submitted, and that these will be staggered over time. First, hospitals are not likely to submit 510(k)s, but will instead contract with third-party reprocessors if such submissions are required.[84] Only approximately twenty-three third-party reprocessors are reported to

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[83] See supra note 5 (proposing an alternative to the FDA Proposed Strategy).

[84] See Transcript of May 5-6, 1999 FDA/AAMI Conference on the Reuse of Single-Use Devices at 167 (statement of Frank Sizemore, Central Service Manager, Wake Forest University Baptist Medical Center and Representative, American Society of Healthcare Central Service Providers) ("The idea of presenting a 510(k) for reprocessing is very interesting. From a health care perspective, hospitals I doubt, seriously doubt, would ever consider doing such a thing. I don't think that would cause a flood of applications.").

exist –a far more manageable number.[85] Second, each reprocessor must develop data demonstrating the safety and effectiveness of each product prior to submission. Because single use devices are not designed to be cleaned and to retain their functional requirements, ADDM believes that reprocessors will be unable to generate such data for most devices. The net result of twenty-three reprocessors submitting 510(k)s/PMAs for a small subset of single use devices is a modest increase in the number of premarket reviews. In order to assist the agency with this increase, Congress has appropriated $1,000.000 of FDA's fiscal year 2000 budget for reprocessed device review.[86] Moreover, FDA simply lacks the legal authority to exempt devices because of regulatory burdens.[87]

II. Specific Comments on the Eight Components of the FDA Proposed Strategy

The FDA Proposed Strategy specifically discusses eight components in FDA's plan to regulate reprocessing of single use devices. While ADDM believes that those components have not been adequately developed by FDA to enable it to provide

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[85] See id. at 231 (statement of Anne Cofiell, C.R.C.S.T., Consultant, Cofiell Consulting Services and Representative, International Assoc. of Healthcare Central Service Material Management) ("I don't know whether these numbers are correct, but we heard that there were 23 companies out there that are reprocessing single use disposable items.").

[86] See Pub. L. No. 106-78, 113 Stat. 1135, 1159 ("For necessary expenses of the [FDA] . . .(5) $154,271,000 shall be for the [CDRH] . . of which $1,000,000 shall be for premarket review, enforcement and oversight activities related to users and manufacturers of all reprocessed medical devices authorized by the [FDC Act] . . . .").

[87] See Hoffmann-La Roche Inc. v. Weinberger, 425 F. Supp. 890, 894 (DDC 1975) ("[T]he argument that FDA [] lacks the administrative resources to insure compliance with section 355 cannot be permitted to postpone to some indefinite future date the implementation of the required preclearance approval of new drug applications). See American Pub. Health Ass'n v. Veneman, 349 F. Supp. 1311, 1317 (DDC 1972) ("When, as is the case here, Congress has shown an awareness of a problem and has acted accordingly, it seems inappropriate for the agency to adopt procedures which extend the grace period far beyond that envisioned by the statute, and which effectively stay implementation of the congressional mandate that drugs in the marketplace be both safe and effective.").

meaningful comment, ADDM has considered each component and summarized its impressions below.

A. Reconsideration of FDA's Current Policy on Single Use Device Reprocessors

FDA claims that the FDA Proposed Strategy would enable FDA to regulate reprocessors in the same manner that it has regulated OEMs. This is not the case since reprocessors of "low" and "moderate" risk devices may not be required to file premarket submissions.[88] All reprocessors, whether they reprocess single use devices characterized by the Risk Categorization Guidance as "low," "moderate," or "high" risk, are manufacturers of reusable devices and should be regulated as such. FDA's uniform regulation of all manufacturers will ensure that patients are afforded the same level of protection.

FDA should treat these reusable devices as it would any other reusable device, and require the same data regarding cleaning, sterility, and functionality that have always been required for reusable devices. On September 28, 1999, ADDM submitted a proposed guidance document for premarket review of reprocessed single use devices to FDA.[89] The data that would be submitted under this proposed guidance are consistent with FDA's review requirements for reusable devices. FDA has offered no justification for developing different or less stringent data requirements for reprocessed single use devices.

The FDA Proposed Strategy discusses regulating some subset of reprocessed single use devices as it would new devices. For those devices which fall into FDA's ill-defined "moderate" and "low" risk categories, however, reprocessors would not be required to submit data to FDA. In fact, for "low" risk devices, the agency has advised reprocessors that they will not likely be inspected, thereby decreasing their incentive to comply with any

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[88] In fact, it seems curious that FDA is more concerned about protecting patients from reuse of medical devices when an OEM legitimately designs, manufactures, and labels a reusable product than when a reprocessor, without adequate knowledge of fundamental device design criteria, exposes a second patient to a device that was *not designed* to be reused. There is absolutely no patient safety rationale that could justify this disparate treatment of devices, manufacturers, and patients.

[89] See Letter from Josephine Torrente, Esq., President, ADDM, to David Feigal, Jr., M.D., M.P.H., Director, CDRH, FDA (Sept. 28, 1999).

requirements. Equitable treatment of all manufacturers of reusable devices is mandated under the APA and is necessary to ensure patient safety.

B. FDA's Proposed Categorization Scheme is Unnecessary and Unclear

1. A risk-based classification system for medical devices already exists

Central to the FDA Proposed Strategy is the development and implementation of a risk categorization scheme for the regulation of reprocessed single use devices. ADDM does *not* agree that a new risk-based system should be developed specifically for this subset of reusable devices. In addition to wasting FDA resources, the development of a new scheme delays implementation of premarket submission requirements and continues to jeopardize patient protection.

As initially described in the FDA Proposed Strategy, the new classification scheme classifies a reprocessed single use device into one of three classes –"low," "moderate," or "high" risk– based on criteria loosely identified by FDA. For devices characterized as "low" or "moderate" risk, premarket submissions are not be required despite a lack of device-specific data demonstrating that these devices are safe for use in patients. After substantial public criticism that the FDA Proposed Strategy effectively ignored the risk-based classification system for medical devices put in place by Congress over 25 years ago, an FDA official "clarified" that this new scheme *may* serve only to prioritize FDA review of premarket submissions.[90] This clarification seems mostly a matter of semantics since FDA has not announced deadlines for requiring premarket submissions for "low" and "moderate" risk devices. Developing an elaborate categorization scheme intended to allow the distribution of unapproved devices is a misuse of agency resources.

2. Continued inadequate regulation of most devices

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[90] See Transcript of Dec. 14, 1999 FDA Public Meeting: Reuse of Single Use Devices-FDA Proposed Strategy at 134-35 (statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA) ("I think there's been much misunderstanding in regard to what the scheme is that we're hatching in regard to the premarket process. What we are discussing this afternoon is a scheme to prioritize the submissions of premarket applications, be they 510(k)s, premarket approval applications, whatever, a way to prioritize the receipt and review of these applications.").

Under the FDC Act, premarket submissions must be required of all reprocessed single use devices that are not legally exempted from such a requirement. While FDA has announced that "high" risk devices will be required to comply with this requirement,[91] the agency must clarify whether it intends to *enforce* the premarket submission requirements for devices characterized as "low" or "moderate" risk and, if so, announce timelines for implementation of such enforcement practices.

Premarket control is as essential to the regulation of reprocessed single use devices as it is to the regulation of all other medical devices. Nonetheless, FDA has evidenced its intention to ignore or substantially delay enforcement of the premarket controls for many reprocessed single use devices. For devices characterized as "low" risk, FDA has announced plans to ignore the premarket requirements and to de-prioritize establishment inspections.[92] As for "moderate" risk devices, the FDA Proposed Strategy claims that "FDA would enforce applicable premarket requirements to ensure that the reprocessed device remains . . . safe and effective. . . ."[93] However, for products in this category, FDA then declares that a reprocessor's declaration of conformity to consensus standards may satisfy this requirement. This reliance on consensus standards enables FDA to continue its history of non-enforcement while declaring that the premarket submission requirements are being complied with for "moderate" risk devices.[94]

While the requirement for premarket submissions can be satisfied by an exemption under the FDC Act, such an exemption must be based on device-specific data available for public inspection and comment. In contrast, the FDA Proposed Strategy exempts broad categories of devices from premarket submission by fiat. While factors such as those mentioned in the Risk Categorization Guidance may play a role in making individual exemption decisions, they cannot be used to exempt all "low" risk devices.

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91 See FDA Proposed Strategy at 10.

92 See id. at 10-11.

93 Id. at 11.

94 The FDA Proposed Strategy also discusses time periods for implementation of certain requirements. See FDA Proposed Strategy at 11. ADDM disagrees with the extraordinary long implementation schedule, and advocates the grace periods set forth in the ADDM Strategy.

The FDA Proposed Strategy suggests that all reprocessed Class I and Class II exempt single use devices would be characterized as "low" risk.[95] This would result in automatic exemptions for those devices. Thus, Class I exempt biopsy forceps would be reprocessed without premarket submission despite the additional safety concerns introduced by reprocessing that would place that device in a "high" risk category under the Risk Categorization Guidance.[96] Such a policy would not be consistent with ensuring patient safety. In exempting certain single use devices, FDA and its expert panels did not consider that the device would be subjected to reprocessing and be used in multiple patients. Reuse introduces risks that were not factored into the exemption. If reprocessing truly presented no new risks, then FDA would allow OEMs to relabel their single use Class I and Class II exempt devices as reusable without FDA clearance of a 510(k).

3. The FDA classification scheme is ambiguous

Should FDA proceed with implementation of the Risk Categorization Guidance for any purpose, it must more specifically define the decision-making criteria to prevent the same device from being placed into multiple categories. The FDA Proposed Strategy strongly implies that only Class III devices will fit into the "high" risk category.[97] The FDA Proposed Strategy also concludes that all Class I and Class II exempt single use devices will be "low" risk. Nonetheless, in applying the scheme in the Risk Categorization Guidance, many reprocessed Class I and Class II devices, including exempt devices, must be categorized as "high" risk.

For instance, biopsy forceps and sphincterotomes, which are critical devices with narrow lumens and inaccessible parts that impede cleaning and sterilization, would be categorized as "high" risk (Grade 2 on FDA's Flowchart 1) under the FDA scheme. Nonetheless, in a recent article, the president of the American Society for Gastrointestinal

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95 "The agency anticipates that the low-risk category would include . . . Class I and Class II exempt, and some Class I and II non-exempt" devices. FDA Proposed Strategy at 10.

96 The Risk Categorization Guidance details a method for determining whether a particular reprocessed single use device would be regulated as a "high," "moderate" or "low" risk device under the FDA Proposed Strategy.

97 "Considering the type and regulatory class of SUDs that may be included in [the high risk] category, it is likely that premarket data will be . . . submitted through the premarket approval process." FDA Proposed Strategy at 10.

Endoscopy states that "gastrointestinal endoscopy accessories will likely fall into the FDA-proposed category of 'moderate risk' based on inherent design characteristics and intended use."[98]

Similarly, anesthesia breathing circuits would be "high" risk under FDA's Flowchart 2. This is because of their corrugated, often concentric multiple lumens. and "Y" connectors that could be damaged during single use or reprocessing. jeopardizing performance due to increased potential for leakage and inadvertent disconnection.[99] No performance standards exist for these devices and performance cannot be evaluated on visual inspection alone. Despite these features, the Risk Categorization Guidance cites anesthesia breathing circuits as an example and erroneously concludes that these devices would be "low" risk. The example concludes that the device contains no "components [that] may be damaged or altered by single use [in such a way that] performance of the device may be affected."[100] This conclusion demonstrates a lack of understanding of the device, and compels the conclusion that technically qualified individuals at CDRH must implement the risk categorization scheme. These decisions clearly can not be left in the hands of the reprocessors. Yet FDA still has apparently not resolved the fundamental question of who will categorize devices under its scheme.[101]

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98 James T. Frakes, M.D., M.S., Reuse of Single Use Devices: Lesson in Science, Economics. and Politics, at 11 ASGE News (Dec. 1999).

99 See Letter from Anthony P. Martino, Vice President, Quality Assurance and Regulatory Affairs, Vital Signs Inc. to FDA Dockets Management Branch (FDA Docket No. 99N-4491) (Jan. 14, 2000) ("[Anesthesia Breathing Circuit] SUD tubing is 'corrugated' and does not have a smooth lumen making cleaning difficult . . . [Anesthesia Breathing Circuit] SUD tubing not only 'conveys' gases to the patient, but also transports exhalation gases away from the patient. This presents a source of 'contamination.'").

100 Risk Categorization Guidance at 5.

101 See Transcript of Dec. 14, 1999 FDA Public Meeting: Reuse of Single Use Devices-FDA Proposed Strategy at 153 (statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA) ("I think FDA's going to have to do a categorization run-through of the frequently reprocessed devices, at least, that are on the list, to give an indication of where FDA feels the devices fall out. But I don't think we're going to run through each and every device known to man that may be presented for reprocessing. And I think some of the categorizations and decision-making will

4. Rethinking the categorization scheme flowcharts

FDA has recently clarified that the proposed categorization scheme may serve only to prioritize receipt of premarket submissions for reprocessed single use devices.[102] ADDM disagrees with this approach because of its continued authorization of reprocessing and because of the lack of a deadline for premarket submissions for devices that would be characterized as "low" risk under FDA's scheme.

ADDM agrees with the Risk Categorization Guidance that the three key factors in determining the risk of reusable devices, including reprocessed single use devices, are the inherent risk of the device, the risk of disease transmission/infection, and the risk of inadequate/unacceptable device performance. These factors cannot, however, be assessed across broad categories via flowcharts, but must be evaluated using model-by-model data. ADDM suggests that the flowcharts in the Risk Categorization Scheme be amended as demonstrated in Attachments 1 and 2 hereto. Once modified, these flowcharts should be used only to aid in granting data-based exemptions under the FDC Act.

Both flowcharts are amended by removing the Grade 1 and thereby eliminating the "moderate" risk category. A device whose risk is unknown must be treated as unsafe and ineffective, and will therefore be deemed "high" risk. In addition, in Flowchart 1, question 4 and in Flowchart 2, question 1 are revised to recognize that use of the device, as well as reprocessing, may damage device materials, coatings or components. Flowchart 2 is further amended by deleting questions 2 and 3. The existence of standards and ease of visual inspection are a critical part of a device's 510(k) submission and review, but cannot be used in a flowchart to determine risk.

In addition to these changes, the terminology used in the flowcharts needs clarification to promote consistency. For instance, Flowchart 1 includes the term "narrow lumen" yet it was clear at FDA's December 1999 Stakeholder Meeting that the lumen of a device could be narrow in the eyes of one person and not in the eyes of another.[103]

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have to be downloaded to the people doing it. At least that's my first opinion. But it's a matter of discussion. . . .").

[102] See supra note 90.

[103] See Transcript of Dec. 14, 1999 FDA Public Meeting: FDA's Proposed Strategy on Reuse of Single Use Devices at 156 (statement of David Greenwald, M.D., Chairman, Gastroenterology Endoscopes Subcommittee, American Society for

C. FDA's Draft List of Frequently Reprocessed Single Use Devices

Section three of the FDA Proposed Strategy identifies twenty-two devices that FDA has assembled into its "draft list of frequently reprocessed SUDs." The purpose of the draft list, however, is unclear. The draft list is prefaced by a short one sentence introduction and no further explanation is provided. The draft list is inconsistent with the Risk Categorization Guidance. In that document, FDA properly identifies risk, not frequency of reprocessing, as the most important factor to consider in determining the regulation of reprocessed single use devices.

Section three of the FDA Proposed Strategy fails to specify criteria for a device's inclusion or exclusion from the draft list. Without identifying the criteria by which a device is evaluated, the draft list is not only arbitrary, but it also does not afford interested parties the opportunity to assess whether a particular device should be placed on a future draft of the list nor does this list account for newly developed single use devices. If a device is not on the draft list, it is unclear whether, or when, a premarket submission is required to reprocess that device. In addition, FDA does not provide a mechanism for adding new devices to the draft list. Moreover, the significance of a device's inclusion on the draft list is unclear. FDA must explain clearly the importance of being placed on the list.

Even more important, the approach taken by the draft list is fundamentally flawed. FDA noted correctly at the May 1999 FDA/AAMI meeting that the decision to reprocess a device must be based on specific models of devices.[104] FDA recognized this shortcoming in its Risk Categorization Guidance when it specifically identified a cardiac ablation catheter as a "high" risk device, instead of evaluating "cardiac catheters and guidewires" as identified in the FDA Proposed Strategy's draft list. Similarly, some surgical staplers may present a higher risk to patient health if reprocessed than others.

Testing and Materials) ("[W]hat's a narrow lumen? . . . [FDA] said it didn't have a narrow lumen. I mean it has a narrow lumen compared to other devices . . . .").

[104] One FDA researcher noted that "we need model by model [evaluation] . . . . [We] can't do device, [we] can't do manufacturer, we've go to go model by model. I don't think serial number by serial number yet, but certainly model by model." Transcript of May 5-6, 1999 FDA/AAMI Conference on the Reuse of Single-Use Devices at 78 (statement of Katherine Merritt, Ph.D., Research Biologist, Division of Life Sciences, OST, CDRH, FDA).

FDA's grouping of devices under the umbrella term "frequently reprocessed single use devices" does not take into account the differences between devices that perform similar functions. Instead of a frequency-based evaluation, devices should be evaluated by FDA on a model-by-model basis. The most appropriate and effective process for such evaluation is the premarket submission process. Following such a process will fulfill FDA's stated goal in issuing the FDA Proposed Strategy –"to protect the public health by assuring that the practice of reprocessing and reusing [single use devices] is based on good science."[105]

D. Labeling Regarding the Risks of Reprocessing

The FDA Proposed Strategy suggests implementation of new labeling requirements for single use devices. This suggestion is incompatible with Congress' most recent pronouncements on FDA review of medical device labeling, and it raises potential liability issues for FDA's stakeholders.

1. History of the single use label

For nearly a century, the medical community had routinely reused most medical devices. In the late 1950s, this practice changed when a New Jersey dentist unwittingly used improperly sterilized hypodermic needles and injected nine patients with a fatal hepatitis virus. In response, laws prohibiting the reuse of hypodermic needles were enacted. As similar incidents occurred both in the United States and abroad, organizations such as the Association of Operating Room Nurses became increasingly alarmed at the potential for harm associated with device reutilization and became advocates for strict standards of device cleanliness and performance. FDA and medical device manufacturers began implementing a requirement that certain devices be labeled "single use only."

At the same time, the use of single use devices expanded significantly due to their convenience and efficiency. This was particularly true during the Korean War, when single use plastic fluid containers eliminated the need to remove, re-sterilize, and then return to the battlefield glass bottles filled with IV fluid. Additionally, with the improvement of plastic technology, devices became smaller, more reliable in design, and more effective. They saved space, were lightweight, and eliminated breakage. They also improved patient care. For example, plastic intravenous catheters were more flexible and comfortable than needles and greatly reduced trauma to the patient.

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[105] FDA Proposed Strategy at 7.

Many of the interventional technologies that have revolutionized medicine, such as balloon angioplasty catheters, controlled radial expansion balloons, and tools to repair brain aneurysms, are only possible because of the design features that would be impossible to achieve in a reusable device. Single use devices are designed for optimal performance, not for ease of cleaning. Whereas most reusable devices are easily disassembled, have smooth surfaces, and are made of durable material, a single use device may be seriously compromised or destroyed by cleaning and reprocessing techniques.

In the last ten years, FDA has increasingly focused on the need for OEMs to include labeling for "single use only" on certain devices. For example, in 1992, FDA published in a draft 510(k) guidance document for cortical electrodes, the requirement that the device label specify whether the device is intended for single use or multiple use.[106] In 1996, FDA reclassified acupuncture needles from Class III to Class II with the implementation of special controls including labeling for single use.[107] FDA issued a document in 1998 that required aqueous shunt manufacturers to include a statement that the device is for single use only.[108] Most recently, in a 1999 document addressing the proposed classification for external penile rigidity devices, FDA required that the label address the disposable/single use status.[109] These are only a few examples of the many instances where FDA has required labeling for "single use only." While OEMs have complied with such requirements, the reprocessing industry and others now assert that the single use label is not a FDA requirement, but rather a label to be used arbitrarily by the OEM.[110] That is, they

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106 See FDA Reports and Publications for Specific Products (Aug. 10, 1992). (While this guidance was never formally finalized, Neil B. Ogden, Director, General Surgery Devices, ODE, CDRH, FDA, confirmed that cortical electrode manufacturers must comply with its requirements.) (Personal Communication, Jan. 28, 2000.)

107 See Reclassification of Acupuncture Needles for the Practice of Acupuncture, 61 Fed. Reg. 64616 (Dec. 6, 1996).

108 See FDA Reports and Publications for Specific Products (Nov. 16, 1998).

109 See Proposed Classification for the External Penile Rigidity Devices, 64 Fed. Reg. 62 (Jan. 4, 1999).

110 See AMA Talking Points, AMDR ("Manufacturers choose to label devices as single-use; it is not a FDA requirement"); statement of Timothy Ulatowski, M.S., Director, DDIGD, ODE, CDRH, FDA, at the FDA Satellite Videoconference on the Proposed FDA Strategy for Reuse of Single Use Devices (Panel I) (Nov. 10, 1999) ("[I]t's the

deem "single use only" to be an optional labeling statement. As is evidenced by these examples and many others like them, this statement is wholly untrue.

Others have asserted that OEMs should be required to develop safe and effective reprocessing techniques and then add device-specific instructions regarding select methods of resterilization or reprocessing to their labels. Such statements completely ignore design considerations surrounding single use devices. Some single use devices have failed testing for multiple use. While others have not been tested for multiple use, this lack of testing is generally the result of the OEM's recognition, based on its understanding of the device's design, that the device would fail such testing.

A medical device can only be labeled for what is has been demonstrated to do safely and effectively. All single use devices have been cleared or approved by FDA for one use because they have been demonstrated to be safe and effective when used on a single patient in a single procedure. It is an illogical, hazardous approach to establish a multiple-use label as the "default" label when there are no data regarding a device's safety and effectiveness after reprocessing. The burden has always been on the manufacturer of a reusable device to show that reuse is safe. Reversing the burden would be improper and unprecedented.

2. *The FDA Proposed Strategy –Requirements of the FDC Act*

Furthermore, requiring OEMs to provide, as part of a single use device's labeling, information of which they are aware regarding the potential risks associated with reprocessing would be unlawful. FDAMA prohibits FDA from requiring OEMs to include the potential risks associated with reusing single use devices in their device labeling.[111] FDAMA added to the FDC Act a new section 513(i)(1)(E)(i). That section limits FDA's determination of the intended use of a device that is the subject of a premarket notification to the sponsor's proposed labeling. Thus, FDA may review only that information which the manufacturer included in the draft label or any accompanying information, such as directions for use or promotional materials. FDA has no authority to require that OEMs add information to the label regarding the potential risks of reuse.

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device manufacturer who writes the label for their product. . . . They have to have the data and information to support the claims that they have in labeling . . . . As long as the manufacturers promote their device and the device is used predominantly for the use in the labeling, then we don't take issue with the claims.").

[111] See Pub. L. No. 105-115, 111 Stat. 2296 (1997).

The Senate Report on FDAMA finds that, "[s]imply put. the committee does not want FDA to exceed its jurisdictional responsibilities by incorporating into the review process claims not before the agency for review consideration."[112] FDA will be exceeding the scope of its authority if it requires that OEMs include warnings of the potential risks of reprocessing in single use device labeling.

FDAMA does identify, and a January 1998 FDA guidance document addresses. the "rare instances in which the design of the device or published literature referencing the subject device or a similar device would lead one to believe that there may be an intended use different than that appearing in the labeling."[113] In this exceptional situation. FDA must determine "(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and (II) that such use could cause harm."[114] If both of these criteria are met, then the 510(k) submitter must be provided the opportunity for a consultation with the Director of CDRH where one possible outcome is that FDA will issue a "substantial equivalence letter with limitations" in which the agency may require the inclusion of information about the off-label use for the device.[115]

However, FDA cannot apply the exception in its review of 510(k) submissions for single use devices. "Reuse" is a different intended use than "single use."[116] A new 510(k) is required for "[a] major change or modification in the intended use of the device."[117]

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112 S. Rep. No. 105-43 at 27 (July 1, 1997).

113 See Determination of Intended Use for 510(k) Devices – Guidance for Industry and CDRH Staff, ODE, CDRH, FDA (Jan. 30, 1998).

114 FDC Act § 513(i)(1)(E)(i)(I)(II), 21 U.S.C. § 360c(i)(1)(E)(i)(I)-(II).

115 See id.

116 21 C.F.R. § 801.4 defines "intended uses" as "the objective intent of the persons legally responsible for the labeling of devices." While this section further states that "[i]t may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised," section 205 of FDAMA generally limits FDA review of 510(k)s and PMAs to a sponsor's proposed condition of use, therefore this section prevents FDA from requiring labeling regarding non-proposed uses.

117 Id. § 807.81(a)(3)(ii).

Both prongs of the FDAMA exception must apply before FDA may require the 510(k) submitter to include labeling information regarding an unintended use. Here, reuse is not just an unintended use, but is the opposite use –and one that is actively warned against by OEMs. Therefore, the analysis under the second prong, whether reuse could cause harm, need not be addressed.

3. The FDA Proposed Strategy –Liability issues

FDA has proposed requiring OEMs to include the potential risks associated with reusing single use devices in their labeling.[118] FDA's proposed requirement would have the effect of increasing the likelihood that OEMs, physicians, and hospitals will be subject to costly products liability litigation. For physicians and hospitals that reuse single use devices, FDA's proposed requirement may create additional malpractice claims as a result of the numerous additional warnings that single use device labels would contain.[119]

It is unrealistic for FDA to impose on OEMs the burden of knowing all the potential risks that could result from reprocessing, and, including only those risks known to the OEM may mislead hospitals and physicians into believing that only those risks exist. An OEM cannot predict all the potential hazards that a reprocessor might introduce into a device, or all the potential ways in which the device might fail should the reprocessor improperly handle it. By listing some failure modes, the OEM leaves itself open to liability if the device fails through some other means. For example, if an OEM warns of five risks associated with reprocessing, the OEM may be sued for not listing a different failure mode which materialized.[120]

Rather than require that OEMs warn of the potential risks of reprocessing, FDA should require reprocessors to provide such information and remove the OEM name from the device and its label. In this way, device failures will be reported to the reprocessor and not to the OEM. In addition, such a requirement will decrease OEMs' liability exposure and place the burden for failed reprocessed single use devices where it belongs –on the

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118 See FDA Proposed Strategy at 13.

119 Remarks made by James M. Wood, Esq., Crosby, Heafey, Roach & May, at the FDLI/FDA 43rd Annual Educational Conference (Dec. 16-17, 1999) (transcript unavailable).

120 See MacDonald v. Ortho Pharma. Corp., 394 Mass. 131, 475 N.E. 2d 65 (MA) cert. denied, 474 U.S. 920 (1985).

reprocessor. Leaving the OEM's name on a reprocessed device can wrongfully result in the OEM being dragged into the litigation.

E. Working Definitions for Certain Terms

The FDA Proposed Strategy contemplates the need to establish uniform definitions for four terms and proposes a draft definition for each. While ADDM agrees that standardized definitions would be helpful, ADDM proposes the following alternative definitions.

> **Single Use Device:** a device labeled by the manufacturer, and cleared or approved by FDA, to be used for one procedure on one patient and not to be reprocessed or reused. This term is synonymous with "disposable device."[121]

FDA's definition of single use devices is confusing in that "opened but unused single use device" is different from "single use disposable," rather than a subset of it. FDA's definition also fails to indicate that the intended use is proposed by the OEM and cleared or approved by FDA.

> **Reuse:** the repeated use or multiple use of any medical device, whether a single use device or a reusable device, on different patients with reprocessing between uses.

FDA's definition of reuse inappropriately includes multiple uses of the same device on the same patient. By so doing, FDA has decreased the utility of the term "reuse" by including dialyzers in the term.

> **Reprocessing:** the process to which a used single use device or used reusable device is subjected in an attempt to make the device appropriate for use in another patient. Reprocessing steps may include cleaning, sterilization, functional testing, repackaging and relabeling, among others. Reprocessing does <u>not</u> include steps taken to sterilize an opened but unused single use device, a device whose expiration

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121 This proposed definition has been adapted from a definition stated in the Emergency Care Research Institute's (ECRI's) special report on the reuse of single-use devices. ECRI defines a single-use device as a "[d]evice labeled by the manufacturer to be used for one procedure on one patient and not to be reused. A specific type of disposable medical device." ECRI, Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions, at 43 (1997).

date has expired, or a single use or reusable device provided to the user as non-sterile.

FDA's definition of reprocessing incorrectly includes pre-use sterilization of devices provided to the user non-sterile with instructions for sterilization.

Resterilization: the repeated application of a terminal process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to an acceptable sterility assurance level.

For single use devices resterilization may only be appropriate for opened but unused devices or for devices whose expiration dating has passed prior to use.

F. The Inapplicability and Impracticability of Consensus Standards and Performance Standards

The FDA Proposed Strategy proposes the application of recognized consensus standards and the development of new consensus standards to evaluate the safety and effectiveness of reprocessed single use devices. Such an approach, however, is inadequate because consensus standards are voluntary and do not evaluate the performance of each reprocessed device. FDA has also proposed the development of performance standards to evaluate reprocessed single use devices. Experience has shown that developing performance standards is an extraordinarily slow process. In addition, performance standards would not address present concerns about patient safety. Only submission of a 510(k) or PMA can adequately address the safety and effectiveness concerns raised by reprocessing single use devices.

Consensus standards are too broad to adequately address the safety and effectiveness concerns raised by reprocessing single use devices. A consensus standard would be appropriate to the extent the *practice* of reprocessing needs to be better defined, simplified, and homogenized. Reprocessing single use devices, however, presents issues about the *performance* of individual devices that cannot simply be remedied by conformance to a consensus standard. For instance, consensus standards cannot be used to delineate how the materials used in a single use device will perform after reprocessing. Heightened FDA scrutiny is necessary. The most appropriate form of FDA scrutiny for reprocessed single use devices is a premarket submission.

Moreover, the use of performance standards is impractical. Since the passage of the MDA twenty-four years ago, FDA has issued and implemented only *one* mandatory

performance standard[122] under section 514 of the FDC Act.[123] For FDA to suggest that it can now develop a myriad of performance standards for reprocessed single use devices conflicts with the agency's track record, as well as the agency's own admission that it lacks the resources needed to develop them.

The development of a performance standard that addresses construction, components, testing parameters, measurement of performance characteristics, results, and labeling is a massive undertaking. Even if FDA heavily relied on the support of stakeholders to develop performance standards, practical considerations militate against achieving consensus among the different stakeholders. Moreover, at the May 1999 FDA/AAMI meeting FDA officials acknowledged that a device-by-device, model-by-model evaluation is the only way to adequately assess how and if a device can be reprocessed.[124] A device-by-device, model-by-model evaluation can be effected only through the premarket requirements, not performance standards.

G. Development of Research Program and Public Outreach

Section seven of the FDA Proposed Strategy recommends that FDA "[c]onsider developing a research program on reuse of [single use devices] and explore avenues to publish and disseminate research and other information on reuse."[125] While a research program designed to further study the effects of reprocessing on single use devices may provide useful data, that information cannot supplant the need for reprocessor-specific data demonstrating the safety and effectiveness of a reprocessed single use device. The agency should expend its scarce resources on enforcing the law, not on additional research about an unlawful activity.

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122 In May 1997, FDA issued a final rule in the Federal Register that established a performance standard for electrode lead wires and patient cables. See 62 Fed. Reg. 25477 (May 9, 1997).

123 See 21 U.S.C. § 360d (providing for the establishment of a performance standard to "provide reasonable assurance of [a device's] safe and effective performance" which may include information on "the construction, components, ingredients, and properties of [a] device . . . [and] testing (on a sample basis or, if necessary, on an individual basis) of [a] device.").

124 See supra note 104.

125 FDA Proposed Strategy at 16.

Instead of FDA's assuming the responsibility for producing data on reprocessing, the onus should be on the reprocessor to demonstrate through the premarket submission process that a device is safe and effective. Initiating a research program to develop data that, by law, should be developed by the reprocessing industry is a misuse of agency funding. Rather than fund expensive satellite teleconferences and outreach activities that only further delay resolution of this issue, the agency should enforce the requirements of the FDC Act, including premarket submission requirements. Enforcing the law would obviate the need for extensive outreach.

H. December 14, 1999 Stakeholder Meeting

FDA has held numerous public meetings to discuss the regulation of single use device reprocessors. The meetings are consistently attended by the same stakeholders conveying the same divergent messages. At the end of each meeting, FDA concludes that the issue is complex and "not amenable to simple solutions." The latest of these meetings was held on December 14, 1999, and represents one of the eight components of the FDA Proposed Strategy. FDA appears to believe that the agency cannot protect patients or enforce the law without first obtaining stakeholder consensus. This is wholly untrue. FDA has repeatedly shown that it can enforce the law, even without consensus. Indeed, the agency has enforced certain provisions in the face of strong industry opposition. There is absolutely no reason why FDA needs to achieve a consensus here before it enforces the law by requiring premarket clearance of reprocessed single use devices.

III. Conclusion and Recommendations

The FDA Proposed Strategy perpetuates an environment of FDA enforcement discretion that fails to protect patients from many reprocessed single use devices, fails to regulate reprocessors of these devices as it does manufacturers of all other reusable devices, fails to appropriately allocate agency resources, and fails to enforce the FDC Act. Further discussion of the FDA Proposed Strategy can only serve to delay patient protection. FDA must abandon this approach and immediately require full compliance with the FDC Act by all reprocessors of single use devices. The ADDM Strategy provides a method for implementing these requirements. ADDM again urges FDA to adopt and implement the ADDM Strategy.

Respectfully submitted,

Josephine M. Torrente

JMT/dmb
1486.001/outline.doc

Attachment 1

Infection Potential

Is device non-critical? yes → Grade 0

↓ no

Does device have features impeding cleaning, disinfection or sterilization? yes → Grade 2

↓ no

Does postmarket info suggest increased infection risk over new device? yes → Grade 2

↓ no

Does device contain coatings, materials or components that may be damaged/ altered by **single use or reprocessing**? yes → Grade 2

↓ no

Grade 0

Attachment 2

Failure Potential

Does device contain materials, coatings or components that may be damaged/altered by single use **or reprocessing** affecting performance? no → Grade 0

↓ yes

Grade 2

Attachment C

ADDM Proposed Reviewer Guidance

DRAFT GUIDANCE OUTLINE
FOR
PRE-MARKET REVIEW PARAMETERS
REUSE OF USED SINGLE-USE DISPOSABLE DEVICES

INTRODUCTION

FDA regulates the introduction of medical devices into interstate commerce. A person intending to reprocess a used single use disposable device (USUDD) and market that device for use on subsequent patients has changed the intended use of the device from 'single use' to 'reusable'. FDA has established and published in its guidance document entitled " Deciding When to Submit a 510(k) for a Change to an Existing Device, 510(k) Memorandum #K97-1 January 10, 1997", that such a change in intended use is deemed to be significant since it may have a serious effect on patient safety and efficacy. This guidance document (Labeling, A1) specifically addresses a change from single use to reuse:

> Rather than referring to "intended use" as a determinant in deciding when to submit a 510(k), this guidance identifies several specific labeling changes or modifications that have a major impact on intended use and thus would require the submission of a 510(k). Two common labeling changes that impact intended use and would usually require submission of a 510(k) are:
>
> 1. reuse of devices previously labeled "single use only;" and
>
> 2. changes from prescription to over the counter (OTC).

Consistent with this position, FDA has a long history of having accepted, reviewed and cleared numerous premarket review applications for reusable devices based on their substantial equivalence to safe and effective devices already in interstate commerce. These applications are typically reviewed with a primary focus on demonstrating that reuse can be accomplished in a safe and efficacious manner for both the patient and the healthcare practitioner.

Therefore, in accordance with existing FDA precedent and based on FDA's ability to review applications which specifically address reusable devices, such a person must file with FDA the appropriate pre-market review application (e.g. 510(k), PMA, PDP) prior to introducing the device into interstate commerce.

The intent of this draft guidance document is to provide FDA reviewers and applicant sponsors specific directions regarding information and data which should be submitted to FDA in a submission for a reprocessed used single use disposable device.

In the past, FDA's position regarding reprocessed used single use devices focused on the general absence of adverse event data and concluded that reprocessors need only comply with QSR and/or GMP regulations as an adequate measure to protect the public health (CPG 7124.16 Sec.300.500).

More recently, based on published information, MDR reports as well as FDA's own laboratory testing demonstrating that reprocessing used single use devices may have a significant effect on device safety and efficacy, FDA has now concluded that reprocessors of these devices must file pre-market review applications containing data demonstrating that the individual device may be reprocessed in a safe and efficacious manner for a specific number of reuse cycles. This requirement coupled with the ongoing need for QSR/GMP compliance will provide more appropriate assurance regarding public health protection.

FORMAT/CONTENT

Regulations governing the general content and format of 510(k), PMA and PDP submissions are codified under 21 Code of Federal Regulations, Part 807. These and other regulatory requirements pertaining to the marketing of a new medical device are discussed in guidance documents available from the CDRH Division of Small Manufacturers Assistance (DSMA). Specific guidance regarding the content and format required for 510(k) applications may be found in "Premarket Notification 510(k): Regulatory Requirements for Medical Devices, HHS Publication FDA 95-4158, August 1995."

FDA has already established minimum data requirements for pre-market review of reusable devices. Since a reprocessed used single use disposable device fits the definition of a reusable device, submissions filed pursuant to this guidance must comply with all existing ODE requirements regarding reusable device filings.

SCOPE

This document provides guidance for the pre-market review of reprocessed used single use disposable devices. Reprocessing includes but is not limited to disassembling, cleaning, replacing/refurbishing of components, re-assembling, labeling, packaging and sterilizing a single use disposable device which has already been used on an individual patient and is now intended for use on subsequent patient(s).

PURPOSE

This guidance is intended to:

1. Guide FDA review staff in conducting and documenting the review of pre-market review applications for reprocessed used single use disposable devices;

2. Assist persons (manufacturers, distributors, or importers) in the organization and preparation of premarket submissions intended to support reprocessing of used single use disposable devices;

3. Achieve consistency in meeting the requirements and in the presentation of premarket review data for these purposes.

OVERVIEW

a. Provide a complete overview of the reprocessing procedure. This description should consist of detailed drawings, photographs, and diagrams. Process and product flow should be described including any provision for repairing, replacing and/or refurbishing the device or any of its components.

b. Provide reprocessing procedure details including any use of water, enzyme cleaners, detergents, lubricants, abrasives, brushes, air lines, packaging, labeling and sterilization methods.

c. Include a clear statement regarding the maximum number of reuse cycles allowed as part of the premarket application.

CLEANING

a. The evaluation of the cleaning parameters should demonstrate the effectiveness of the cleaning process independently of any other steps in the process. The applicant should define the endpoint for cleaning, provide the scientific rationale for the endpoint and show how it relates to clinical use. The testing should evaluate the ability of the cleaning step to remove a defined challenge. It is recommended that the challenge be representative of the types to which devices are exposed during clinical use. The test data should demonstrate that the endpoint is consistently achieved for the device intended to be reprocessed.

b. Identify each cleaning method intended for use in the reprocessing procedure along with the identity of each material contained in the device intended for reprocessing.

c. Provide test methodology, specifications and validation data demonstrating that the cleaning methods used are reliable and effective in removing any existing debris including blood, tissue, adhesives, lubricants, etc. when subjected to the maximum number of reuse cycles being applied for in the premarket application. Include limits of detection.

d. Include data demonstrating that the cleaning methods used have no short term or long term adverse effects on the finished device and /or any of its components when subjected to the maximum number of reuse cycles being applied for in the application.

e. Identify processing steps employed to remove all cleaning material residues. Provide analytical test methodology (including sensitivity limits) for residue analysis along with validation data demonstrating the absence of these residues.

f. The application should include an assessment of the level of any residues, (e.g. detergents, lubricants, and germicides) remaining on the medical device after processing including a toxicological evaluation of these residues. This can be satisfied by reviewing the available toxicity data of the particular residual chemical from animal toxicity studies sponsored by the applicant of the chemical or from published literature. This evaluation is needed to determine the potential health risk of the residues remaining on the device to the patient and the end user.

REPROCESSING PARAMETERS

a. Provide feasibility rationale for reprocessing the device.

b. Describe all process parameters including time, temperature, water quality, preprocessing conditions, postprocessing conditions, etc. Identify the factors that affect the effectiveness of the processes and state how they are controlled.

c. Provide the rationale for each process parameter. The process parameters should be based on sound scientific studies which show that each phase of the process achieves its stated purpose.

DESIGN AND COMPONENT CONTROLS

a. Provide the original equipment device manufacturer's (OEM) design parameters and specifications. This should include all materials/components and design changes made to the device by the OEM for the specific device intended to be reprocessed.

The applicant must also demonstrate the ability to address ongoing design changes made to the device by the OEM including changes in materials, components, assembly and sterilization procedures, packaging and labeling. If the OEM design parameters, manufacturing processes and related specifications are not used, then the applicant must provide justification including validation data to support any alternate parameters/specifications intended to be utilized.

b. Establish rationale and minimum criteria for determining whether any individual used single use disposable device is suitable for reprocessing. Factors to be used in making this determination should include the physical and/or microbiological condition of the device at the time it is received for reprocessing.

c. Identify parameters associated with repairing, refurbishing and/or replacing any of the device components as part of the reprocessing procedure. This should include data demonstrating that any such component is equivalent in all aspects of form, fit and function with respect to the indented use of the device, including the number of reuse cycles applied for in the application.

RESTERILIZATION

a. Identify specific sterilization methods (i.e. ETO, gas plasma, steam, radiation, etc.) intended for use in the reprocessing procedure.

b. Submit validation data (including all test protocols) from industry standard protocols/guidances regarding sterility assurance levels (SAL's). The resterilization validation data should support the maximum number of reuse cycles petitioned for the device in the application. These data should also demonstrate the suitability of the resterilization process in terms of final device function.

c. Pursuant to FDA's "Guidance for Industry Modifications To Devices Subject to Premarket Approval - The PMA Supplement Decision Making Process, August 6, 1998," the applicant should specifically include data which addresses the following:

(16.1) Pyrogens. If the device will be labeled as non-pyrogenic, state what process controls will be used to control pyrogens; and, state what method, such as the Limulus Amebocyte Lysate (LAL) or USP Rabbit test, will be used to determine that each lot is non-pyrogenic. This information is required for devices that contact blood or cerebrospinal fluids.

(16.2) Sterilization by User. The labeling for devices intended to be sterilized by the user must identify one validated method of sterilization. The instructions should be detailed and specific enough for the user to follow and obtain the required SAL. The instructions should also adequately describe any precautions to be followed such as: special cleaning methods required; any changes in the physical characteristics of the device that may result from reprocessing and resterilization, especially those which may affect the safety, effectiveness, or performance; and any limit on the number of times re-sterilization and reuse can be done without adversely affecting the safety,

REPROCESSED DEVICE TESTING

1. Functional Testing:

The applicant should provide data demonstrating that the reprocessed device meets all physical, chemical, microbiological and/or performance specifications assigned by the OEM at the time the device was initially introduced into interstate commerce. These data should directly relate to safety and efficacy regarding the device's Intended Use/Indications for Use. In satisfying this requirement, the applicant may not rely upon or otherwise reference any or all portions the premarket review application filed by the OEM and cleared/approved previously by FDA for the device.

Testing should evaluate the performance of the reprocessed used single use disposable device up to and including the maximum number of reuse cycles applied for in the application including laboratory bench testing, animal studies, and/or clinical studies where appropriate.

2. Sterility Testing:

The applicant should provide data from the sterilization validation program demonstrating that devices subjected to the reprocessing procedures meet or exceed a minimum SAL of 6.0 at the maximum number of allowed reuse cycles.

3. Residue Testing

To ensure safe conditions of use of the medical device following processing, the applicant must present data which demonstrate that there are no residues remaining on the device or that the process cycle removes the residues to a nontoxic level. The applicant must also present data which

demonstrate that there is no accumulation of residues over the maximum number of reuse cycles for the device which could present a health risk to the patient and the user.

PACKAGING/LABELING

a. The submission must contain proposed labels, labeling, and other promotional materials sufficient to describe the device, its indications for use/intended use, and the directions for use [21 CFR 807.87(e)]. Labels include the information affixed directly to the device and its packaging. Labeling also includes the users manual, service manual, and any other information that accompanies the device.

   Submit revised Instructions For Use including a statement that the device is a reprocessed Single-Use Device, the number of reprocessing cycles allowed as well as already performed on the device, and the revised expiration date for the device.

b. The labeling must meet the requirements of 21 CFR Part 801 as it relates to a determination of intended use. ODE will concentrate on the following:

   Subpart A, Sections 801.4 and 801.5, related to intended uses and adequate directions for use.

   Subpart B, Sections 801.109 and 801.116, related to prescription devices and commonly known directions.

c. Submit new product labeling, omitting OEM name/logo, and replacing it with the reprocessor's name. Include documentation verifying the removal of the OEM name from the device itself.

d. Provide package integrity data including ship testing and stability data in support of a maximum expiration date.

e. Statement regarding use of and/or exposure to latex during any reprocessing procedures.

List of Frequently Reprocessed Single Use Devices

Medical Specialty Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Cardio- vascular	Angiography catheter	870.1200	N	510(k)	II	DQO	high
	blood pressure cuff	870.1120	N	510(k)	II	DXQ	low
	cardiac ablation catheter	unclassified	N	PMA	III	LPB	high
	cardiac guidewire	870.1330	N	510(k)	II	DQX	high
	compressible limb sleeve	870.5800	N	510(k)	II	JOW	low
	Electrophysiology recording catheter	~~870.1130~~ 870.1220	N	510(k)	II	DRF	high
	intra aortic balloon catheter	870.3535	N	~~510(k)~~ PMA	III	DSP	high
	needle [1]	~~870.1390~~	N	510(k)	II	DRC	high
	percutaneous transluminal coronary angioplasty (PTCA) catheter	unclassified	N	PMA	III	LOX	high
	percutaneous transluminal angioplasty (PTA) catheter	unclassified	N	510(k)	II	LIT	high
	syringes[2]	~~870.1670~~ 870.1650, unclassified	N	510(k)	II	DXT	high
	trocar	870.1390	N	510(k)	II	DRC	moderate
Respiratory	breathing mouthpiece	868.5620	~~Y~~ N	~~N/A~~ 510(k)	I	BYP	low

[1] FDA should clarify which device is intended here. 21 C.F.R. § 870.1390 is applicable only to trocars, not needles.

[2] FDA should clarify which devices are intended. 21 C.F.R. § 870.1670 is applicable only to syrnige actuators and not to syringes.

List of Frequently Reprocessed Single Use Devices

Medical Specialty Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Respiratory (Cont)	endotracheal tubes	unclassified	N	PMA	III	LZN	high
	masks	868.5550	Y	N/A	I	BSJ	low
	oral and nasal catheters[3]	868.5350	Y	N/A	I	BZB	low
	respiratory therapy and anesthesia breathing circuits	868.5240	Y	N/A	I	CAI	moderate
	tracheobronchial suction catheter	868.6810	N	510(k)	I	BSY	high
Gastro-enterology/ Urology	biliary sphincterotomes	876.4300	N	510(k)	II	KNS	high
	biopsy needles	876.1075	N	510(k)	II	FCG	high
	endoscopic guidewires	876.1500	N	510(k)	II	KOG	low
	endoscopic staplers	876.4400	N	510(k)	II	FHN	low
	extraction balloons/baskets	876.1500	N	510(k)	II	KOG	high
	non-electric biopsy forceps	876.1075	~~Y~~ N	~~510(k)~~ N/A	~~II~~ I	FCL	high
	trocar	876.5090	N	510(k)	II	FBQ	low
	urethral catheters	876.5130	N	510(k)	II	KOD	moderate
Nephrology	hemodialysis blood tubing	876.5820	N	510(k)	II	KOC	moderate
OB-GYN	laparoscopic dissectors	884.1720	Y	N/A	I	HET	low
	laparoscopic graspers	884.1720	Y	N/A	I	HET	high
OB-GYN (Cont)	laparoscopic scissors	~~8~~884.1720	Y	N/A	I	HET	high
	trocar	884.1720	N	510(k)	II	HET	low
Orthopedics	arthroscopy instruments	888.1100	~~N~~ Y	510(k)	~~II~~ I	HRX	low

[3] FDA should clarify which device is intended here. 21 C.F.R. § 868.5350 is applicable only to nasal oxygen catheters, and not to oral catheters.

List of Frequently Reprocessed Single Use Devices

Medical Specialty Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Orthopedics (Cont)	carpal tunnel blade	888.4540	Y	N/A	I	LXH	moderate
	drill bits	~~878.4540~~ 878.4820	Y	N/A	I	HTW	low
	external fixation device	878.3900 878.3910	Y	N/A	I	FZF, FYH	low
	flexible reamers/drills	~~886.4070~~ 878.4820	~~Y~~ N	~~N/A~~ 510(k)	I	GEY, HRG	low
	saw blades	878.4820	~~Y~~ N	~~N/A~~ 510(k)	I	GFA, DWH, GEY, GET	low
	surgical drills	878.4820	~~Y~~ N	~~N/A~~ 510(k)A	I	GEY, GET	low
Surgery	biopsy forceps	876.1075 876.4300 874.4680 ~~874.4680~~	N	510(k)	II	FCL KGE HFB BWH JKK	high
	biopsy needles	878.4800	Y	N/A	I	DWE	high
	burr	878.4820	~~Y~~ N	~~N/A~~ 510(k)	I	GFF, GEY	low
	electrosurgical electrodes/ handles/ pencil	876.4300	N	510(k)	II	HAM, GEI, FAS, FEH, KNS	moderate
	endoscopes	876.1500	N	510(k)	II	many	high

List of Frequently Reprocessed Single Use Devices

Medical Specialty Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Surgery (Cont)	endoscopic blades	876.1500	N	510(k)	II	GCP, GCR	moderate
	endoscopic guidewires	876.1500	N	510(k)	II	GCP, GCR	low
	enodoscopic staplers	888.4540	Y	N/A	I	HXJ	moderate
	fascia holders	878.4800	Y	N/A	I		moderate
	laproscope	884.1720 876.1500	N	510(k)	II	HET, GCJ	low
	laser fiber delivery systems	878.4810 874.4500 ~~874.4370~~ ~~874.4496~~ ~~878.4810~~ 886.4390 884.4550 886.4690	N	510(k)	II	GEX, EWG, LXR, LMS, LLW, HQF, HHR, HQB,	low
	scissor tips, removable inserts	878.4800 888.4540 884.4520 874.4420	Y	N/A	I	LRW, HHR, HDK, HDJ, JZB, KBD	moderate
	surgical cutting accessories	878.4800 874.4420	Y	N/A	I	GDZ, GDX, GES, KBQ, KAS	moderate
	trocar	874.4420 876.5090	Y	N/A	I	KABK BGKCI	moderate
	trocar	874.4420 876.5090 876.1500 870.1390	N	510(k)	II	FBQ.FBM, GCJ, DRC	moderate

List of Frequently Reprocessed Single Use Devices

Medical Specialty Service	Device	Regulation #	Exempt (Y/N)?	Type of Premarket Submission	Class (I, II, III)	Procode	Risk Category
Plastic Surgery	stapler	878.4800 882.4190	Y	N/A	I	GAG, GEF, FHM, HBT, HBS	moderate
Laboratory	glucometer lancets	878.4800	Y	N/A	I	FMK	low
Ophthalmic	keratome blade	886.4370	N	510(k)	I	HMY, HNO, MYD	high
	OR drapes	878.4370	N	510(k)	II	KKX	moderate
	phacoemulsification needle	886.4670	N	510(k)	II	MUS	high
Infection Control	OR gowns	878.4040	N	510(k)	II	FYA	low
	sharps containers	880.5570	N	510(k)	II	MTV, FMI	low
	syringes, piston	880.5860	N	510(k)	II	FMF	high
General Hospital	infusion pump, implanted	unclassified	N	PMA	III	MDY, LKK	high
	syringe, irrigating	880.6960	Y	N/A	I	KYZ, KYY	low
Dental	braces, plastic	872.5470	N	510(k)	II	DYW	high
	braces, metal	872.5410	Y	N/A	I	EJF	high
	burr	872.3240	Y	N/A	I	EJL	moderate

ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

December 7, 1999

BY FACSIMILE

David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Further Evidence of Increased Patient Risk with Reprocessed Used Single-Use Medical Devices

Dear Dr. Feigal:

ADDM is a trade association of original device manufacturers dedicated to protecting patient safety through proper regulation of single use device reprocessing. In a November 22, 1999 letter, ADDM summarized sixteen studies already on file at FDA and supplied the FDA with new evidence of increased patient risk with reprocessed used single-use medical devices. The purpose of this letter is to further supply the FDA with published evidence of the existence of valid scientific data that confirms the physical, microbiological, and functional performance failures associated with reprocessed used single-use medical devices. Three published literature reports on the dangers of reprocessing used single use devices are enclosed.

The first article entitled "Parental Report of Pediatric Tracheostomy Care," draws a correlation between the increased incidence of pneumonia in pediatric patients and the reuse of tracheostomy tubes, which are devices labeled as "single-use only." Tracheostomy tube reuse was reported by 55% of the 60 participants. Approximately 60 percent of the pediatric patients on whom reprocessed tracheostomy tubes were used developed pneumonia within the previous year, compared to only 25 percent of pediatric patients on whom new tracheostomy tubes were used in the same time period. Other potential variables such as patient age, diagnosis, method of tube cleaning, and frequency of tube change showed no correlation to increased incidence of pneumonia, leaving tracheotomy tube reuse as the only predictor of pneumonia. The author's conclusion questions the safety of reusing these single-use devices.

The article entitled "Iatrogenic Central Retinal Artery Embolization: A Complication of Cardiac Catheterization," reports that a 57-year old man experienced a sudden loss of vision in one eye during a cardiac catheterization for coronary angiography after a heart attack. The loss of vision was due to a reprocessed catheter, the tip of which fragmented and lodged in the patient's central retinal artery on the optic nerve head of the patient's right eye, leaving that eye with only light perception vision. At the end of a six-month follow-up, the patient's right eye vision remained only perception and nasal projection of light. The catheter fragmentation was attributed to the reautoclaving process and the reuse of the single-use device. The authors recommend compliance with manufacturers' single use label to prevent complications such as this.

The third article, "A Pseudo-Outbreak of *Aureobasidium* Lower Respiratory Tract Infections Caused by Reuse of 'Single-Use' Stopcocks During Bronchoscopy," highlights a very important public health issue associated with reprocessing used single-use devices: antibiotic resistance. The report reveals that reprocessed stopcocks labeled "single-use only" led to a pseudo-outbreak in which nine patients were misdiagnosed as being infected with *Aureobasidium*, a genus of the fungus known as "black yeast." Had this

erroneous diagnosis involved a different organism, these patients would have likely received unnecessary antibiotic treatment for their "infections." This article demonstrates the potential that reprocessed single use devices may be serious contributors to the growing problem of antibiotic resistance in the U.S.

This sample of reported incidents further indicates the need for the FDA to recognize the important patient safety issues associated with reprocessing used single-use devices, and fully enforce the Food, Drug and Cosmetic Act. including the requirements for premarket submissions.

Sincerely.

Josephine M. Torrente

JMT/dmb

cc: Stephen Brobeck
Joan Claybrook
Marcia Crosse
Peter Derschang
John Fielder. Ph.D.
Linda Golodner

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Alan Slobodin
Jennifer Thomas
Edward Truschke
Eleanor Vogt

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Iatrogenic Central Retinal Artery Embolization: A Complication of Cardiac Catheterization

DIETRICH HALLERMANN, MD, AND GURINDER SINGH, MD

A 57-year-old man with a myocardial infarction was subjected to cardiac catheterization as a follow-up study for his heart problem. The catheter, made for one time use only, was reautoclaved and used sometime before catheterizing this man. A small fragment of this catheter dislodged while guiding the parent catheter into coronary vessels with a metallic guide-wire. The fragment traveled getting lodged in the central retinal artery of the right eye leaving the eye with only light perception vision. The catheter fragment could be seen in the central retinal artery at the optic nerve head.

The investigative and therapeutic procedures like cardiac and carotid catheterization and external carotid therapeutic embolisation, etc, have great advantages in the management of patients and are routine procedures. But simultaneously, these procedures have potential risks of serious complications. Ocular complications like central retinal artery occlusion or embolization during cardiac catheterization,[1] as a complication of external carotid therapeutic embolization[2] and during carotid angiography[3-4] are well documented. Like most of the other patients, one man developed sudden loss of vision in his right eye because of central retinal artery embolization caused by a catheter fragment. To the best of our knowledge, central retinal artery embolization by cardiac catheter fragment has never been reported. This needs discussion because necessary precautions must be observed in the future to prevent such a dreadful complication.

From the University Eye Clinic, Hamburg, West Germany.

Reprint requests to Augenklinik, University of Hamburg, Martinistrasse 52, 2000 Hamburg 20, West Germany. (Priv. Doz. Dr. D. Hallermann, MD).

Report of a Case

A 57-year-old man was brought to the University Eye Clinic with sudden loss of vision in his right eye that had developed the day before. He was subjected to cardiac catheterization for coronary angiography for a follow-up study of his myocardial infarction that he suffered three months earlier. The catheter was introduced through the right cubital vein and was being guided up into the coronary vessels when he noticed loss of vision in his right eye. That procedure was stopped there only. Three hours after the episode the attending physician recorded vision of light perception in right eye and full vision (1.0) in the left eye. Next day he was brought to us.

The patient was seen by us about 20 hours after the episode. He had vision of light perception only with nasal projection of light with eccentric-seeking in the involved eye. The pupil was mid-dilated, reacting normally in consensual light but very sluggishly to direct light. On ophthalmoscopic examination, a green crystalline foreign-body was seen within the central retinal artery on the optic nerve head (Fig 1). Retinal arteries were constricted with mild venous engorgement. Nasal disc margin was slightly blurred with filling up of the disc-cup and showing mild papilledema. The fundus background was paler than the left fundus but there was not much of retinal edema to present a picture of a fully developed cherry-red spot. Anterior segment, ocular media, and intraocular pressure (IOP B/E 14 mm Hg) were normal. The left eye did not show anything significant except for the absence of consensual light reflex.

Vasodilators and eyeball massage were not helpful in dislodging the foreign-body into the branch artery. Mild retinal edema remained for about two months after which it started regressing. Six months later the fundus looked normal (as in the left eye). Even after six months fol-

Figure 1 Cardiac catheter fragment occluding the central retinal artery at its point of bifurcation on the optic nerve head (arrow pointing to catheter fragment).

low-up the vision in the right eye remained only perception and nasal projection of light. The foreign-body was still on the optic nerve head within the central retinal artery though the venous congestion had regressed and the arteriovenous ratio was normal.

Discussion

Central retinal artery embolism usually is consequent to dislodging the atheromata of carotid arteries, postrheumatic vegetations, myxomas, or following iatrogenic or self-inflicted trauma by intravenous injections of drugs and chemicals.[5] Air and dye entering the circulation during angiographic techniques are other potent causes.[1] Recently, a case has been seen with branch artery occlusion as a complication of selective external carotid embolization done in a case of juvenile nasopharyngeal angiofibroma.[2] In the present case, the green crystalline embolus seen in the central retinal artery was a piece of cardiac catheter that broke from the catheter and lodged in the right central retinal artery. This, to our knowledge, happens to be the first of such a complication of cardiac catheterization.

The retrospective analysis revealed that it is a common practice with cardiology units of most hospitals to reautoclave the plastic cardiac catheters and reuse one catheter on five to six patients before discarding. According to the manufacturers, every catheter is to be used only once. But, because of the cost involved, large number of cardiology units do not adhere to these instructions and reuse the catheters on many patients after reautoclaving. In the present case also the cardiac catheter was reautoclaved against the instructions and it is presumed that this made the catheter friable leading to this unusual and dreadful complication. This fragmentation might have been further enhanced because of the metallic guide-wire used to guide the tip of the catheter into the specific artery. It is suggested that cardiology units should comply with the manufacturer's instructions and not take the risks of complications like the one that developed in our case. Also, the quality of the material used for these delicate instruments should be improved.

The patient was seen about 20 hours after the episode of sudden loss of vision. Had the patient been diagnosed earlier with central retinal artery embolus the early active treatment like paracentesis, vasodilators, or eyeball massage might have helped to move the embolus further into the branch artery. Some useful vision may then have been saved. On clinical assessment, the artery obstruction was not total, postischaemic retinal edema was not severe enough to produce a full bloom cherry-red spot and residual light perception showed that the retina was getting partial or minimal blood supply. (Retinal angiography was denied by the patient because of the previous investigation leading to this complication.) Beginning vasodilators and eye massage 20 hours after the obstruction was already too late to think of regaining useful vision and also the irregular shape of the catheter fragment made it stick at the branching of the central retinal artery. Considering the optic nerve head diameter as 1.5 mm the size of the catheter fragment was about 0.16 mm (Fig 2) and this big embolus with sharp

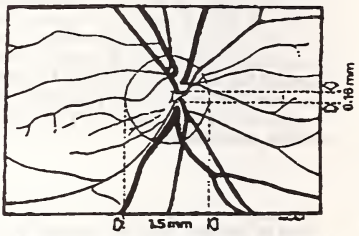

Figure 2 Taking the average diameter of the optic nerve head as 1.5 mm the width of catheter fragment is about 0.16 mm.

irregular edges could not be expected to move further into the branch retinal artery. Minimal residual blood supply left the retina with vision of light perception and nasal projection.

Anatomical predisposition of the right common carotid artery to get cardiac emboli was reason for this fragment to travel into the right arterial circulation. It is very unusual for such a foreign-body to travel all the way up into the ophthalmic artery and then ultimately get lodged in a terminal part of the central retinal artery.

Comment

To conclude, it is strongly recommended or suggested that though potential, yet dreadful, risk factors must be considered seriously before subjecting the patients to investigative procedures like cardiac catheterizations especially when these are done for follow-up studies only. Also, due care should be taken both by physicians and surgeons and also the manufacturers in selecting the quality of materials used in different instruments.

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In Reply.—Wilson and McClatchey raise important questions that deserve careful analysis. Because it has been shown that esotropes with a high accommodative convergence/accommodation ratio or a nonaccommodative convergence excess do require larger amounts of surgery than other esotropes,[1] we intentionally excluded such patients from our study. We only included acquired esotropes in whom the near deviation and distance deviation were approximately equal. We are surprised that Wilson and McClatchey believe that this group of esotropes requires a larger amount of surgery for a given deviation than congenital esotropes. All of the popular strabismus textbooks and journal articles we are aware of do not recommend a different surgical formula for congenital esotropes than for decompensated accommodative esotropes in whom the near deviation equals the distance deviation. We therefore thought it was appropriate to combine these two patient groups in our study. Nevertheless, because of the questions raised by Wilson and McClatchey, we reanalyzed our data separating congenital esotropes from acquired esotropes. For the 15 congenital esotropes in our study the response to surgery had a significant inverse correlation with axial length ($r = -.502$, $P < .05$). For the 21 acquired esotropes in our study the response to surgery did not correlate significantly with axial length ($r = -.381$, $P < .10$). We were concerned that because all of our acquired esotropes were beyond the age of rapid ocular growth, and, consequently, there was a much narrower range of axial lengths in these patients than in the congenital esotropes, that the number of patients would be too small to establish significance for what appeared to be a "trend," although there were more patients in this group than in the congenital esotropia group. Because our data collection is ongoing, we chose to further analyze patients with acquired esotropia by including the additional 14 patients we have now studied who met all the criteria of our original study. In these 35 patients the correlation of response to surgery with axial length was significant ($r = -.371$, $P < .05$).

Of greater importance is the suggestion by Wilson and McClatchey that the correlation we found between axial length and response may have really been a reflection of the fact that patients with smaller eyes tend to have larger deviations (congenital esotropes), and, according to Mims, larger deviations have a greater response to surgery than smaller deviations. To address this question it is important to determine the partial correlation coefficient for response to surgery with axial length, adjusting for deviation. This statistical text will reveal how response correlates with axial length if the influence of any variation in deviation is eliminated. For 36 patients in our original study, the partial correlation coefficient of axial length and response, adjusting for deviation was still significant ($r = -.3890$, $P < .02$).

Our study confirms theoretical calculations that axial length should be important in determining the response to [illegible] surgery.[2] Although Mims and others have found a unimodal dose-response curve, to our knowledge there is no satisfactory theory as to why it should be so. We believe our data suggest that the bimodal response found in strabismus surgery for esotropia may reflect the fact that larger deviations occur in patients with smaller eyes, and, because of the smaller axial length in patients with large deviations, the response to the same amount of surgery is greater.

Finally, although we did calculate response in degrees per millimeter, we did not actually generate a dose-response curve in this study, not did we extrapolate to zero, as Wilson and McClatchey suggested. Although it is clinically easier to measure patients using prism diopter notation (because that is how our prisms are calibrated), we believe that the use of degrees for calculations more accurately describes the deviation of an eye and its change in position after surgery.

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Retinal Artery Embolism Following Cardiac Catheterization

To the Editor.—In the March 1989 issue of the ARCHIVES, Pe'er et al[1] reported various fundus findings secondary to retinal emboli 1 day following cardiac valve surgery in 10 of 81 patients. They did not mention the number of eyes involved. Even then, this alarmingly high number (12%) suggests the need for more extensive preoperative and postoperative ocular workup to prevent and treat these complications that will go undetected otherwise. This study reveals the fact that retinal emboli following cardiac surgery are underdiagnosed, underreported, or both.

Although since the late 1970s only one report[2] addressing the subject of perioperative retinal emboli after open heart surgery has been published, cases of retinal emboli following cardiac catheterization[3] and therapeutic external carotid embolization[4] have been reported in the 1980s. My colleague and I reported a case of central retinal artery embolization by cardiac catheter fragment.[3] Our patient, a 57-year-old man, underwent cardiac catheterization for coronary angiography as a follow-up study of his myocardial infarction. The fragmentation of the tip of the catheter was related to the reautoclaving and reusing of the disposable catheter against the manufacturer's instructions, and to the metallic guidewire used to guide the catheter into the specific artery. The visual acuity in the involved eye was reduced to light perception after embolism.

I recommend that potential ocular risk factors must be considered and discussed with the patients before subjecting them to cardiac or cardiovascular procedures.

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Parental Report of Pediatric Tracheostomy Care

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ABSTRACT. Bahng SC, VanHala S, Nelson VS, Hurwitz EA, Roloff DW, Grady EA, Lewis CC. Parental report of pediatric tracheostomy care. Arch Phys Med Rehabil 1998;79: 1367-1369.

Objective: There are little data on the actual care given pediatric tracheostomy patients in their homes. Information on the use of supplies and on techniques and frequency of care is valuable for a better understanding of the needs of this population.

Design: Questionnaires were distributed by mail or at clinic visits from May 1995 to June 1996 to a convenience sample of tracheostomized patients at the University of Michigan Pediatric Physical Medicine and Rehabilitation clinic.

Setting: Tertiary care clinic.

Results: Clean technique for suctioning was reported by 96.7% of subjects and the rest reported sterile technique. Fifty percent of subjects reported reusing suction catheters. Cleaning solutions used to clean suction catheters for reuse varied. Tracheostomy tube reuse was reported by 55% of subjects. Sixty percent of those who reused tracheostomy tubes had had pneumonia within the previous year, whereas only 25% of those who never reused the tracheostomy tube had pneumonia in the same time period.

Conclusions: Suctioning frequency, suction catheter, and tracheostomy tube reuse and cleaning methods are variables that warrant further investigation of safety and efficacy.

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MANY PEDIATRIC PATIENTS require a long-term tracheostomy for airway access, mechanical ventilation or both.[1] Home care is a reasonable goal for most children with a tracheostomy. Studies have shown that home tracheostomy care, in conjunction with proper parental training, equipment, follow-up visits, and home nursing care, can be as safe as hospital care and, in most cases, more beneficial to the child's growth and development.[1-3] Home care for respiratory technology–assisted patients has also been shown to be more cost effective than institutional care.[4] Although home tracheostomy care has been evaluated for safety and cost effectiveness, and the literature describes and evaluates the proper training and preparation of parents,[5] an extensive search of the literature found no studies describing the actual methods and supplies used in the home. Such information would contribute to a better understanding of the needs of this population, providing recommendations in the training of home caregivers and helping to increase cost effectiveness. We asked parents of pediatric patients with tracheostomies to report use of supplies, techniques, and frequency of tracheostomy care in the home, and the incidence of pneumonia within the past year.

METHODS

Questionnaires were distributed by mail or at clinic visits from May 1995 to June 1996 to a convenience sample of children with tracheostomies followed at the University of Michigan Pediatric Physical Medicine and Rehabilitation Clinic. Of 90 questionnaires distributed, 60 were returned—an overall return rate of 67%. Patients ranged in age from 9 months to 28 years, with a median age of 7.5 years; 35% of the sample was male. Length of time for which the patient had a tracheostomy ranged from 1 to 15 years, with a median of 4 years ($\bar{x}$ = 4.8yrs). Diagnoses of the patients were: neuromuscular problems, 63%; lung disease, 18%; congenital central hypoventilation syndrome and VACTERL syndrome, 12%; and airway problems, 7%. Lung disease category is comprised of patients with congenital diaphragmatic hernia, bronchopulmonary dysplasia, lymphangiectasia, or multiple congenital anomalies. In the neuromuscular category were patients with spinal cord injury, neuromuscular disease, cerebral palsy, dwarfism, myelodysplasia, brain tumor, stroke, traumatic brain injury, and neurofibromatosis. Eighty percent (48 of 60) of the patients used a ventilator. This study sample is reflective of patients followed in our clinic. Data collected in this study depended on parental report since no verification of the responses through charts or suppliers was made. The questionnaire respondent is referred to as a "subject," whereas the recipient of care is referred to as "patient." (The home caregiver and questionnaire respondent was usually a parent, but in a few cases a patient who was old enough to complete a questionnaire was also the respondent.)

Frequency calculation and univariate analysis was performed using Epi Info 6.04.[6] Multiple regression analysis using STATA 4.0[7] was performed to identify which variables played a role in recurrent infections.

RESULTS

General descriptive data. Of patients who used a ventilator, 10 used a bilevel positive airway pressure machine and 38 used a volume ventilator. Hours of ventilator use ranged from 1 to 24 hours, with 16 patients using the ventilator 24 hours a day. Forty-five percent (27 of 60) of the patients were reported to have had pneumonia within the past year, with 12 subjects reporting one episode, 7 subjects reporting two episodes, 3 subjects reporting three episodes, and 2 subjects reporting four episodes. Three subjects did not indicate the number of pneumonias. Inner cannulas were used by 26 of 60 (26.7%) patients. Thirteen (21.7%) used a cuffed tracheostomy tube; 12 of the 13 used an air cuff and one subject used a foam cuff.

Suctioning. Suctioning was performed once every hour by 13.6% (8), once every 1 to 4 hours by 40.7% (24), once every 4

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to 8 hours by 20.4% (12), and less frequently than once every 8 hours by 25.4% (15). Use of clean technique when suctioning was reported by 58 (96.7%), and only 2 (3.3%) reported using sterile technique. Clean gloves were used by 43 (71.7%) of the subjects, sterile gloves were used by 10 (16.7%), and 7 (11.7%) reported using no gloves. No association was found between glove usage and reported pneumonia.

Fifty percent of the subjects reported reusing suction catheters and the others reported using sterile catheters. Of those who reported reusing suction catheters (30), 80% (24) cleaned their catheters with vinegar, 17% (5) used water, and 13% (1) used another solution. No statistically significant association was found between the use of sterile or reused suction catheters and reported pneumonia within the past year. Number of catheters used per month is shown in table 1. The median number of catheters used per month was 60; the mean was 108.

Tracheostomy care. Brand A (Shiley[c]) tracheostomy tubes were used by 28 (46.7%) patients, brand B (Bivona[d]) by 19 (31.7%), and brand C (Portex[e]) by 13 (21.7%). Fifty-five percent (33 of 60) reported reusing the tracheostomy tube and the rest reported never reusing the tracheostomy tube. Reuse of the tracheostomy tube was correlated with a higher incidence of pneumonia. Approximately 60% (20 of 33) of those who reused the tracheostomy tube reported pneumonia within the past year, whereas only 25% (7 of 27) of those who *never* reused reported pneumonia. Age, type of tracheostomy tube, diagnosis, and frequency of tube change were tested along with tube reuse using logistic regression. Among these variables, reuse of the tracheostomy tube was the only predictor of pneumonia. The odds ratio for tube reuse with pneumonia as an outcome was 5.6 (confidence interval 1.2 to 26; $p = .03$). The R^2 value was .12.

Frequency of tracheostomy tube change is presented in table 2. Frequency of tube change correlated with the patient's age, with older patients tending to change less frequently. Seventy-two percent (31 out of 43) of patients younger than 13 years reported changing the tube weekly to twice monthly, whereas 24% (4 out of 17) of older patients reported changing at this frequency. Seventy percent (12 out of 17) of older patients and only 23% (10 of 43) of younger patients changed the tube monthly or less frequently than every month. Those who changed the tube more frequently were more likely to reuse the tracheostomy tube. Sixty-six percent of those who changed weekly to twice monthly reused, whereas only 9% of those who changed monthly to less than every month reused their tubes. Reuse of the tracheostomy tube correlated with a higher incidence of pneumonia, whereas the frequency of tube change and age did not.

Of those who reused their tracheostomy tubes (33 subjects), 40.6% (13) used hydrogen peroxide to disinfect the tube, 21.9% (7) used soap and water, 12.5% (4) used vinegar, and 25% (8) used a combination of solutions (hydrogen peroxide, vinegar, and soap and water). No association between pneumonia and the method of disinfecting the tracheostomy tube was found.

Table 1: Suction Catheters Used Per Month

Catheters (no.)	Patients (no.)
2-10	4
11-25	4
30-35	16
40-50	3
60	4
90-100	6
105-155	6
168-200	4
200-299	3
300 plus	5

Table 2: Frequency of Tracheostomy Tube Changes

Frequency	Patients (no.)
2/day	1
1/day	2
1/week	27
2/month	8
1/month	19
<1/month	3

DISCUSSION

Suctioning

A comparison of clean versus sterile tracheostomy care technique and levels of pulmonary infection in the hospital setting has shown that clean technique does not lead to more infections.[6] Many parents are taught to use clean technique in the home because sterile technique is not only too cumbersome and costly, but also rarely is strictly carried out. The majority of respondents in our study (58 out of 60) reported using clean technique, consistent with the current trend.

A physician survey on the care of children with tracheostomy found that approximately 50% (31 out of 64) of physicians recommended suctioning on an "as needed" basis, whereas 35% (23 out of 64) recommended suctioning at least hourly.[7] In our sample, 13.6% suctioned hourly. It would be valuable to know whether suctioning frequency is "as needed" or at physician direction, especially considering the potential harmful side effects of endotracheal suctioning.[8]

The Centers for Disease Control (CDC) recommend that a sterile catheter be used for each series of suctionings of patients in the hospital. The CDC has made no recommendations for patients in the home care setting, however, where the risk of acquiring multiple antibiotic-resistant organisms is lower.[9] Fifty percent of our study sample used sterile catheters and the others reused suction catheters. No association was found between sterile versus reused suction catheters and reported pneumonia.

A study by Shabino and coworkers[10] tested the effectiveness of a three-step disinfecting process involving hydrogen peroxide, 100°C soapy water, and 100°C rinse water. This study found the three-step method of disinfecting the suction catheter to be effective under laboratory conditions but did not investigate the matter of defining a practical and cost effective method for home caregivers.

Our study showed vinegar to be the most common (24 out of 30) solution for cleaning the suction catheter for reuse. Although no previous studies have tested the effectiveness of vinegar to disinfect suction catheters, our study indicated that reused suction catheters cleaned with vinegar were not associated with a higher incidence of pneumonia when compared with sterile catheters. Current literature does not address the effectiveness of the cleaning methods used in the home setting or offer guidelines for reuse of the suction catheter. It is evident that further research needs to be done in this area to evaluate and improve the methods used by home caregivers.

Tracheostomy Care

Very little research has addressed the frequency of tracheostomy tube changes or offered guidelines for reusing tracheostomy tubes. The guidelines for tube changes that do exist are contradictory.[11] In our sample, age of the patient was strongly

correlated with the frequency of tube change. Age of the patient affects the size of the tube, and smaller tubes may necessitate more frequent changes to prevent plugging. Although younger patients changed tubes more frequently and reused tubes more than older patients, age was no predictor of pneumonia.

Reuse of the tracheostomy tube in our sample was found to correlate with a higher incidence of pneumonia. Other factors, such as method of disinfecting the tube, frequency of tube change, patient age, diagnosis, and type of tube, were not predictors of pneumonia. The R^2 value of .12 indicates that the regression equation only predicts about 12% of the variability. Although this is not very high, it is significant enough to be of clinical concern. Another aspect of tracheostomy care that needs to be evaluated is the method of cleaning and disinfecting the tracheostomy tube. Little exists in the current literature regarding this matter. Subjects in our sample reported using hydrogen peroxide, vinegar, soap and water, or a combination of solutions. The results of our study strongly suggest the need for evaluating the safety of reusing the tracheostomy tube in the home.

CONCLUSION

This was a study of reported home management of tracheostomy care in children. Descriptive data of home care were obtained regarding suctioning, tracheostomy care, supplies, and cleaning and disinfecting practices. Correlations of various factors with pneumonia were made. Reuse of the tracheostomy tube was the only statistically significant predictor of pneumonia. Research is needed to evaluate the safety of home care practices that may improve the health of children with tracheostomies as well as increase the cost effectiveness of their home health care.

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A Pseudo-Outbreak Of Aureobasidium Lower Respiratory Tract Infections Caused By Reuse Of "Single Use" Stopcocks During Bronchoscopy

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BACKGROUND: Reuse of medical devices labeled for single use has become increasingly widespread as hospitals try to save money. OBJECTIVE: To investigate, control, and report, an apparent outbreak of lower respiratory infections due to *Aureobasidium* spp. DESIGN: Hospital-based outbreak investigation. SETTING: University-affiliated hospital. PATIENTS: Ten bronchoalveolar lavage (BAL) fluid cultures from nine patients grew *Aureobasidium* between June and August 1998; whereas, respiratory specimens from only two patients grew *Aureobasidium* during the preceding six years. RESULTS: No patient was judged to have true infection due to *Aureobasidium* either before or after bronchoscopy. Nine of the 10 bronchoscopies that yielded *Aureobasidium* were performed in the outpatient bronchoscopy suite. The aureobasidium isolates were not associated with any one bronchoscope. Observation of bronchoscopy procedure revealed that plastic stopcocks labeled for single use were repeatedly reused on different patients during BAL. There was no record of how many times each stopcock was being reused. After each use the stopcocks were placed in an automated disinfection machine designed for bronchoscopes. Culture of the stopcocks after they had been "disinfected" yielded a heavy growth of *Aureobasidium*, while cultures of samples from the automated disinfection machine were negative. Reuse of the stopcocks was halted, and during the following six-month period, *Aureobasidium* spp. were not isolated from any BAL specimen. CONCLUSIONS: Reuse of medical equipment designed for single use is potentially hazardous, especially if no quality control system is in place to monitor sterility and function after reprocessing.

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Infectious Diseases Society of America

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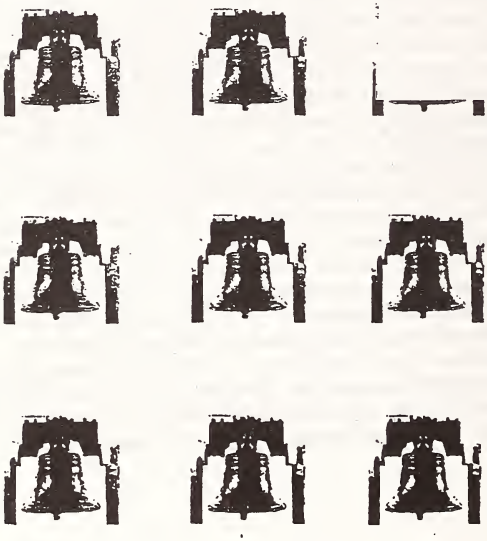
PROGRAM & ABSTRACTS



PENNSYLVANIA CONVENTION CENTER

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ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

November 22, 1999

BY FACSIMILE

David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

Re: Evidence of Increased Patient Risk With Reprocessed Single Use Medical Devices

Dear Dr. Feigal:

As you are aware, the Association of Disposable Device Manufacturers (ADDM) and its member companies have submitted many studies to FDA demonstrating serious patient safety risks associated with reprocessed single use medical devices. This scientific data has been supported by results of studies conducted in the Center for Devices and Radiological Health's (CDRH) Office of Science and Technology (OST), by independent hospital studies submitted to FDA, by published literature reports and by actual patient injuries and device malfunctions reported to FDA through the MedWatch system. Despite the volumes of such data on file at FDA, CDRH officials continue to claim publicly that there is little or no credible scientific evidence available demonstrating that the reuse of used disposable medical devices is unsafe. Most recently, at a nationally televised FDA videoconference on November 10, in response to a question regarding data of which FDA is aware, the Director of OST stated that, "We haven't had any formal submissions of data on which to make a call for reuse decisions." This statement is a serious misrepresentation of the ADDM studies and other scientific submissions filed with CDRH over the past year and misleads the public. The purpose of this correspondence is to summarize key studies which have already been submitted to or conducted by FDA and to present CDRH with three additional scientific studies of reprocessed single use devices. The attached abstracts verify the existence of valid scientific data confirming the physical, microbiological and functional performance failures associated with reuse of disposable medical devices. FDA's repeated failure to acknowledge patient risk data, such as those described below, runs counter to the Agency's mandate to protect patients from unsafe and ineffective devices.

Original Equipment Manufacturer (OEM) Data

For example, one OEM has submitted six studies that consistently demonstrate lack of sterility associated with used single use biopsy forceps reprocessed by major, third party reprocessors and awaiting reuse in patients. The consistency of these results was confirmed after a recent FDA inspection of one of these reprocessors revealed that the reprocessor's sterilization method was ineffective. Because these long, thin plastic-sheathed devices were not designed to be cleaned, the reprocessor's "validated cleaning and sterilization" procedures include vacuum drying to remove residual water and cleaning fluids. Once the devices are dry, they are exposed to ethylene oxide (EtO) gas in an attempt at sterilization. This "sterilization," however, must fail because the bacterial spores present on the forceps are dry and encased in a hard protective shell that

forms on drying. EtO cannot penetrate this shell and destroy these spores. During the next use, however, when the spores are humidified, they again become viable. Despite these independent findings which verify the OEM results, FDA continues to ignore the OEM data.

FDA Data

CDRH's failure to recognize and respond to the patient safety issues raised by these data is compounded by its recent attempts to minimize or discredit the results of studies performed in OST. At the November 10 videoconference, rather than discuss the scientific evidence of patient risk, FDA responded to questions about these studies by dismissing them, stating that they were not intended to be exhaustive.

FDA appears willing to discuss only those "data" which serve its apparent goal – minimal regulation of disposable device reprocessors. In furthering this goal, FDA aired taped comments of a physician-researcher noted for his pro-reuse stance during the FDA panel discussion with no comments provided to balance his views. As a device user, this physician should have been included in the user panel where his statements could have been responded to by other doctors and researchers. Instead, his comments were given undue importance because of their apparent adoption by FDA. Importantly, neither the physician nor FDA mentioned the safety risks demonstrated by the doctor's own research presented at the May FDA/AAMI meeting.

Published Literature

Similarly, during the user panel discussion another pro-reuse physician stated, in error, that FDA had been unable to reproduce the results of a published German study (Roth, K. Zentral Sterilisation 1999; 7:(2) 84-96) which demonstrated lack of sterility of reprocessed disposable devices. At least two FDA panelists were aware that FDA had not even attempted to reproduce that study. Nonetheless, the FDA panel failed to interject and clarify that the German data was unchallenged by FDA, again ignoring or discounting any patient safety risk. By virtue of its silence, FDA allowed the public to be misled regarding the validity of that study.

MedWatch

Finally, FDA has repeatedly stated that its Medical Device Reporting database suggests that problems may exist with reprocessed single use devices, but has discounted the reports in this database because, in FDA's opinion, the device failure often cannot be definitively linked to the reprocessing. All failures associated with reprocessed used single use devices are directly attributable to the reuse. If the device is being used a second, third or sixth time, the device must have functioned properly the first time – as intended. If the device had been used once and discarded, in accordance with its labeling, it would not have failed. Exhaustion of the device's safety margins by reprocessing will cause the device to fail, perhaps by a failure mode that has also occurred with new devices. This overlap in failure modes does not change the cause of the failure in the reprocessed device. Any suggestion to the contrary can only be viewed as a conscious attempt to confuse the issue and ignore the public health concerns associated with reuse of used disposable medical devices.

FDA's willingness to disregard MDR reports which it deems not "definitively linked" to reprocessing is also inconsistent with the Agency's traditional use of the MDR database. FDA has consistently held manufacturers responsible for reported device malfunctions and patient injury even when the link between the device and the injury is tenuous. For example, if a practitioner uses a medical device in a way that was clearly not intended and reports a device failure, that failure is attributable to the manufacturer. Nonetheless, under FDA's current thinking, it appears that failures associated with reprocessed single use devices must be definitively linked to the reprocessing prior to seriously considering them as an indication of the risk of reprocessing.

Despite its admonitions that reports in the Medical Device Reporting database do not definitively demonstrate patient risk for reprocessed disposable devices, FDA has allowed the inference that the database does demonstrate lack of patient risk. At the November 10 videoconference, FDA failed to correct a panelist's statements that this database amounts to a "staggeringly extraordinary safety record." It is telling that twice during that same panelist's comments, however, he stated that when a reprocessed device fails during use he throws it away – never filing an MDR report. The apparent safety record of reprocessing will continue to be characterized as extraordinary if measured by a system in which device failures are disregarded. FDA seems content to declare that there are no patient injuries in a system in which no one is either reporting or looking for them.

* * * * *

FDA has failed to recognize the important patient safety issues associated with reprocessing of single use devices despite the volumes of data to the contrary. The risks of reprocessing disposable devices have been demonstrated by various groups with various devices, yet FDA has not been motivated to appropriately regulate this practice. The Agency's congressional mandate to presume that reprocessed single use devices are unsafe until proven otherwise will not be served by awaiting a proven public health disaster before taking action.

Sincerely,

Josephine M. Torrente

JMT/dmb

cc: Stephen Brobeck – The Consumer Federation of America
Joan Claybrook – Public Citizen
Marcia Crosse – General Accounting Office
Peter Derschang – Association of Operating Room Nurses
Hon. Richard Durbin – United States Senate
Hon. Anna Eshoo – United States House of Representatives
John Fielder, Ph.D.
Janet Franek, RN – Association of Professionals in Infection Control
Linda Golodner – National Consumers League
Philip Grossman, M.D.
David Hennage, Ph.D. – American Nurses Association
Jane Henney, M.D. – FDA
Jeff Kang, M.D. – HCFA
Larry Kessler, ScD – FDA Office of Surveillance and Biometrics
Gene Kimmelman – The Consumer's Union
Richard Kozarek, M.D.
Karen Laing, RN – Society of Gastroenterology Nurses and Associates
Christopher Lavanchy -- ECRI
Dirksen Lehman
John Manthei
Don Marlowe – FDA Office of Science & Technology
Abbey Meyers – National Organization for Rare Disorders
Ann Marie Murphy
Kevin Murray – Medical Devices Canada
Gerald Naccarelli, M.D. – North American Society of Pacing and Electrophysiology
Douglas Nelson, M.D. – American Society for Gastrointestinal Endoscopy
Cynthia Pearson – National Women's Health Network
Michele Pearson – CDC
Joseph Perkins – Association for the Advancement of Retired Persons
Stacey Rampy

Mary Beth Savary-Taylor – American Hospital Association
Lynn Sehulster – CDC
Frank Sizemore – American Society for Healthcare Central Service Professionals
Alan Slobodin
Larry Spears – FDA Office of Compliance
Jennifer Thomas – Association of Professionals in Infection Control
Edward Truschke – The Alzheimer's Association
Tim Ulatowski – FDA Office of Device Evaluation
Hon. Fred Upton – United States House of Representatives
Zeger Vercouteren – EUCOMED
Elke Vogt – BV Med

Re-Use of Devices: Cleaning Issues

Katharine Merritt, Vicki Hitchins, Terry Woods, Stanley Brown
FDA CDRH Office of Science and Technology

Date: May 5, 1999 (public presentation)*

Objective: To obtain data on cleaning efficacy with used and simulated re-use devices

Methods: Percutaneous Transluminal Coronary Angioplasty (PTCA) balloon catheters made by various manufacturers were obtained after a single use. The catheters were exposed to 10% bleach and the guide wire lumen was flushed with 10% bleach. The devices were then placed into water with detergent with enzyme

Unused PTCA catheters were deliberately contaminated with organisms and protein and then EtO sterilized, then tested for sterility.

Results: Observations for Used Devices:

The guide wire lumens were often full of blood which was sometimes clotted and the lumen not patent.

Inability to remove the contrast dye in some balloon channels led to the formation of crystals which plugged the balloon or balloon channel. A plugged channel will usually not be apparent until the balloon is put into use – which could be in the next patient.

Attempts to remove blood in the balloon manifold port may result in bleach being driven into the manifold and not recognized as being there.

Observations for Simulated Reuse Devices:

About half the catheters grew organisms in the middle sections.

Conclusions: PTCA models do not all behave the same way. Some seem to clean easily while other seem to be always plugged. Some guide wire lumens kink easily, get clogged or leak.

This is a device-by-device, model-by-model issue which cannot be standardized.

* This information was abstracted from a public presentation. FDA has not made a study report available for public inspection.

Effect of Use and Simulated Reuse on Materials and PTCA Balloons and Catheters

Stanley Brown, Katharine Merritt, Vicki Hitchins, Terry Woods
FDA CDRH Office of Science and Technology

Date: May 5, 1999 (public presentation)*

Objective: To determine the effects of cleaning and reuse on device materials

Methods: Unused Percutaneous Transluminal Coronary Angioplasty (PTCA) balloon catheters were exposed to defibrinated sheep's blood. The devices, and used PTCA catheters, were then cleaned, packaged and EtO sterilized before being analyzed for mechanical integrity and functional performance.

Results: Analysis of Used PTCA Catheters:
n=330

The guidewire tubes of a number of balloons were curled p inside the balloon after cleaning indicating that the balloon had been stretched during use. This is not manufacturer specific – it is operator specific.

Some balloons were stretched due to overinflation while others were shrunk due to reprocessing and EtO sterilization. These changes may be material specific and cannot be generalized.

Analysis of Simulated Reuse Catheters

Changes in balloon diameter of simulated reuse PTCA catheters vary with the catheters. This may be due to the different levels of rigidity of the different balloons.

Balloon size varied by 10% outside of manufacturer specifications. so that the physician may be using a different balloon size altogether from what she originally chose.

Reprocessed balloons are stickier than new balloons.

Conclusions: The effects of cleaning solutions on "a material called plastic" is material specific, not generic. Not all devices are the same as their specifications.

A physician using a reprocessed PTCA catheter may be using a balloon that is growing in the patient.

* This information was abstracted from a public presentation. FDA has not made a study report available for public inspection.

Evaluation of Reprocessed Ethicon Endo-Surgery, Inc. Single-Use Medical Devices

Ethicon Endo-Surgery Inc.

Date: January 27, 1999 (submitted to FDA)

Objective: To perform a rigorous analysis of reprocessed medical devices labeled for single use, using validated test methods and finished device specifications. These devices were awaiting reuse in additional patients.

Methods: Various single-use surgical instruments were studied. These included tissue staplers, scissors, clamps, needles, clip appliers, graspers and cutters.

Reprocessed used single use devices were obtained from hospital shelves where they were awaiting reuse in patients. They were subjected to physical, microbiological and functional testing to determine whether or not they complied with original device specifications.

Results: Observations and/or product failures:

n=180 [20 each of 9 device groups]

	Product Integrity	Foreign Material	Performance
Shears/Scissors	Fail	Present	Fail
Cutters	Fail	Present	Fail
Clamps/Graspers	Fail	Present	Pass
Staplers	Fail	Present	Fail
Clip Appliers	Fail	Present	Pass
Veres needles	Fail	Present	Pass

Virtually all of the reprocessed devices examined were found to contain dried blood, body fluid, and/or tissue that had not been removed by the cleaning process. In addition, device integrity and functional performance failures were found to be causally related to the reprocessing procedures.

Conclusions: Reprocessed single use devices demonstrate compromised device integrity and altered the device safety and efficacy profiles. Using such devices on more than one patient will jeopardize patient safety.

Reuse Testing Performed on Single Use Medical Devices
U. S. Surgical Corporation

Date: February 4, 1999 (submitted to FDA)

Objective: To perform a rigorous analysis of reprocessed medical devices labeled for single use, using validated test methods and finished device specifications.

Methods: Various single-use surgical instruments were studied. These included tissue staplers, scissors, clip appliers and cutters.

Unused single use devices were subjected to a reusable device qualification protocol to determine the feasibility of reuse. These devices were systematically and repeatedly challenged with microbiological indicators, cleaned, sterilized and assessed for compliance against original release specifications.

Results: Observations and/or product failures:

n=54

	N	Sterility	Functional
Surgical Staplers	24	6	4
Scissors/Retractors	12	2	1
Clip Appliers	12	0	3
Cutters	6	2	6
Totals	54	10 (19%)	14 (26%)

Device sterility, integrity and functional performance failures were found to be causally related to the reprocessing procedures.

Conclusions: Subjecting the single use disposable devices tested in these studies to reprocessing procedures commonly associated with reusable devices, compromised device integrity and altered the device safety and efficacy profiles. Using such devices on more than one patient will jeopardize patient safety.

Analysis of Reprocessed Single-Use Devices
Boston Scientific Corporation

Date: January 27, 1999 (submitted to FDA)

Objective: To perform a rigorous analysis of reprocessed medical devices labeled for single use, using validated test methods and finished device specifications.

Methods: Commercially reprocessed single use biopsy forceps were obtained from hospital shelves awaiting reuse in patients. They were subjected to physical, microbiological and functional testing to determine whether or not they complied with original device specifications.

Results: Observations and/or product failures:

n=55

	Product Integrity	Foreign Material	Sterility
Biopsy Forceps			
Test 1 (n=21):	Fail (85%)	Present	Fail (4/5)
Test 2 (n=34):	Fail (57%)	Present	Fail (17/20)

Virtually all of the reprocessed devices examined were found to contain dried blood, body fluid, and/or tissue that had not been removed by the cleaning process. In addition, device integrity and functional performance failures were found to be causally related to the reprocessing procedures.

Conclusions: Reprocessed single use biopsy forceps demonstrate compromised device integrity and altered the device safety and efficacy profiles. Using such devices on more than one patient will jeopardize patient safety.

Quality Assurance on Reprocessing Accessories for Flexible Endoscopes-Just How Clean are Cleaned Instruments Really?
Zentral Sterilisation; International Journal of Processing and Sterile Supply
Wiesbaden, Germany

Date: 1999 (submitted with this abstract)

Objective: The aim of part one was to ascertain the safety of reprocessed endoscopic accessories following a standardized reprocessing method, based on customary hospital practice. The aim of part two was to determine the sterility of single use biopsy forceps that had been subjected to commercial reprocessing procedures and were awaiting reuse in patients. A preliminary cost evaluation was also included to clarify the economic feasibility of reprocessing.

Methods: In part one, various types of unused single use and their reusable device counterparts were studied. These included biopsy forceps, papillotomes and a reusable dormia basket. All instruments were subjected a contamination regimen simulating a worst case scenario. They were then cleaned, disinfected/sterilized and assessed for degrees of cleanliness and sterility. In part two, thirty-five reprocessed single use biopsy forceps were tested for sterility according to standard sterilization assurance protocols. Reprocessing and repair costs were determined and compared with the cost of purchasing original devices.

Results: Part One: Cleaning - % Effectiveness:

	Reusable	Single Use
Biopsy Forceps	88.6% (13/113 cps)	39.5% (63/104 cps)
Papillotomes	96.7% (6/178cps)	73.1% (42/156 cps)

Sterility :

	Sterile	Non-sterile
Trial 1: n=90	30	60 (50%)
Trial 2: n=57	15	42 (74%)

Part Two: Observed Failures:
Sterility: 6/35 not sterile

Conclusions: Neither adequate cleaning nor adequate disinfection/sterilization was achieved in the majority of devices tested. Instrument design impeded reliable reprocessing. Eighty-three percent of the reprocessed biopsy forceps tested were not sterile. The potential cost savings associated with reuse are considerably lower than commonly assumed

Letter to Larry Spears; Director CDRH Office of Compliance III
R. David Hambrick III, RN
Director, Gastrointestinal Laboratory
Montclaire Baptist Medical Center

Date: October 11, 1999 (submitted to FDA)

Objective: To determine if commercially reprocessed disposable biopsy forceps, which had been used and reprocessed only once, were sterile and suitable for use on subsequent patients.

Methods: Twenty five (25) single use biopsy forceps that had been used once were commercially reprocessed and sent to an outside independent testing laboratory for sterility and pyrogens testing.

Results: USP Sterility Test (n=20): Non-Sterile 14/20 (70%)

USP Pyrogens Test (LAL) (n=5): Pyrogens 0/5 (0%)

Conclusions: Based on this test, the reporter has changed his point of view concerning the viability of reprocessing disposable biopsy forceps.
He states:

> "I am now convinced that current technology does not allow the effective reprocessing of single use forceps."
> "Continuing to allow this practice is an all too real threat to patient safety."
> "With FDA oversight, reprocessors would only be able to market devices that FDA verifies are safe and working properly....".

Sterility and Bioburden Testing of Commercially Reprocessed Biopsy Forceps
Boston Scientific Corporation

Dates: September 17, 1999 (submitted to FDA)

Objective: To determine the sterility of single use biopsy forceps that had been subjected to commercial reprocessing procedures and were awaiting use in patients.

Methods: Samples of commercially reprocessed biopsy forceps were obtained from hospital shelves awaiting use on patients. Some samples were tested for bioburden and other samples were tested for sterility according to standard sterilization assurance protocols.

Results:

Observed Failures:

	n	Bio-Burden	Sterility	Physical	Functional
Study	10	5/10	4/10	-	-

Conclusions: This study provides evidence that the reprocessed biopsy forceps tested are not sterile and do not meet the required sterility assurance level of 10^{-6}, implied by the device label. These results would indicate that the biopsy forceps do not meet FDA criteria for a medical device intended to be reused.

Examination of Devices Commercially Reprocessed And Declared to be Sterile
Boston Scientific Corporation

Dates: September 17, 1999 (submitted to FDA)

Objective: To determine the sterility of single use biopsy forceps that had been subjected to commercial reprocessing procedures and were awaiting use in patients.

Methods: Samples of commercially reprocessed biopsy forceps were obtained from hospital shelves awaiting use on patients. Some samples were tested for sterility according to standard sterilization assurance protocols. Other samples were subjected to light microscopy, scanning electron microscopy and photoelectron spectroscopy.

Results:

Observed Failures:

	n	Bio-Burden	Sterility	Physical	Functional
Study	17	-	9/9	5/8	-

Conclusions: "All these results, investigating the present state of the art of reprocessing endoscopic accessories, show that these single use biopsy forceps cannot be reprocessed safely and reproducibly to sterile condition, even with so called validated reprocessing methods."

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Methods: Samples of commercially reprocessed biopsy forceps were obtained from hospital shelves awaiting use on patients. Some samples were tested for sterility according to standard sterilization assurance protocols. Other samples were subjected to light microscopy, scanning electron microscopy and photoelectron spectroscopy.

Results:

Observed Failures:

	n	Bio-Burden	Sterility	Physical	Functional
Study	18	-	9/14	1/4	-

Conclusions: "All these results, investigating the present state of the art of reprocessing endoscopic accessories, show that these single use biopsy forceps cannot be reprocessed safely and reproducibly to sterile condition, even with so called validated reprocessing methods."

Analysis of Reprocessed Single Use Devices
Boston Scientific Corporation

Dates: September 17, 1999 (submitted to FDA)

Objective: To determine the sterility of single use biopsy forceps that had been subjected to reprocessing procedures and were awaiting use in patients.

Methods: Various samples of reprocessed biopsy forceps manufactured by different companies were obtained from hospital shelves awaiting use on patients. Some samples were tested for sterility according to standard sterilization assurance protocols. Other samples were subjected to functionality testing and destructive visual (microscopic) analysis.

Results:

Observed Failures:

	n	Bio-Burden	Sterility	Physical	Functional
Study	9	-	2/4	-	3/5

Conclusions: Reprocessing single use devices of this type cannot be accomplished in a reliable or safe manner . The practice compromises sterility assurance and jeopardizes patient safety.

Bioburden Testing of Reprocessed Biopsy Forceps
Boston Scientific Corporation

Dates: September 17, 1999 (submitted to FDA)

Objective: To determine the sterility of single use biopsy forceps that had been subjected to commercial reprocessing procedures and were awaiting use in patients.

Methods: Samples of commercially reprocessed biopsy forceps were obtained from hospital shelves awaiting use on patients. Bioburdens (aerobic and fungal) and Microbial ID of colony growth were recorded.

Results:

Observed Failures:

	n	Bio-Burden	Sterility	Physical	Functional
Study	4	3/4	-	-	-

Conclusions: "Based on the results obtained from this bioburden test, it is obvious that the tested units were contaminated and not suitable to be used on new patients even though it was claimed that the units were sterilized with ETO."

Field Quality Engineering Report,
Evaluation of Reprocessed Ethicon Endo-Surgery Single Patient Use Devices
Ethicon Endo-Surgery, Inc.

Date: October, 1999 (submitted with this abstract)

Objective: To investigate the effects of reprocessing on single patient use devices and examine possible degradation in device quality.

Methods: A total of 37 samples of reprocessed single patient use devices were obtained for study. The sample population was obtained randomly from hospital shelves and included clip appliers, clamps, sleeves, cautery devices, needles, staplers, coagulating hears, trocars and cutters. All samples were assessed for package integrity, product integrity and product performance criteria.

Results: Observed Failures:

Packaging (n=37):	17/37 (46%)
Product Quality (n=12):	6/12 (50%)
Foreign Material/Contam. (n=12):	6/12 (50%)

Multiple failures were observed and attributed directly to reprocessing. These included tears and/or breaks in the device packaging, off-axis bends and kinks in linear instruments, damaged protective sheaths in electrocautery devices, cracked/chipped trocars and corroded clip appliers (blood/proteinaceous matter). In addition, performance failures were observed with several clip appliers and linear staplers.

Conclusions: Based on device design and materials, reprocessing single use devices of this type cannot be performed reliably and/or in a safe and efficacious manner. Such reprocessing jeopardizes patient safety as well as the safety of health care providers who use them.

R & D Report:
Changes n Electrophysiology Catheters During Reprocessing or Reuse
Biosense Webster

Date: October 15, 1999 (submitted with this abstract)

Objective: To investigate the effects of reprocessing on electrophysiology catheters manufactured by the Biosense Webster company.

Methods: Part 1:
Thirty two (32) reprocessed EP catheters were obtained from local hospitals; an additional 2 reprocessed EP catheters were obtained from a commercial reprocessor. These 34 catheters were then compared to a control population of 39 new, unused catheters.
Part 2:
Thirty three (33) reprocessed EP catheters were obtained from hospitals and/or commercial reprocessors and evaluated.

All devices were examined for physical, electrical and mechanical characteristics.

Results:

Observed Reprocessing Related Failures:	Part 1	Part 2
Proteinaceous matter contamination:	> 70%	21.2%
Shaft discoloration/scratches:	> 90%	3%
Reduced piston force:	28%	-
Reduced tip bending moment:	12%	-
ETO residuals	38%	9%
Thrombogenicity (n= 6)	-	50%

Broken seals	-	6%
Bends	-	21.2%
Electrical	-	3%

Mechanical, electrical and material degradation were observed in the reprocessed samples. Factors responsible for these failures included chemical (detergent)/physical abrasion, ETO degradation/residuals, and repeated clinical use in excess of device design limits.

Proteinaceous material as well as foreign material residues were also observed. Reprocessed devices tested for thrombogenicity (in-vivo canine model) were found to be significantly more thrombogenic than controls.

Conclusions: The physical, mechanical and electrical integrity of the design parameters are seriously compromised by subjecting these devices to reprocessing procedures. The findings demonstrate that reuse of these single patient use EP catheters cannot be achieved in a safe and efficacious manner, and has the potential to result in patient injury.

Evaluation of Re Furbished Single Use Medical Devices
Cordis

Date: October 27, 1999 (submitted with this abstract)

Objective: To investigate the physical and functional effects of reprocessing on Percutaneous Transluminal Angioplasty (PTA) and Percutaneous Transluminal Coronary Angioplasty (PTCA) devices manufactured by the Cordis company.

Methods: Twenty seven (27) samples of PTA and PTCA catheters were obtained after having been subjected to commercial reprocessing in Germany. Packaging and device integrity parameters were assessed against original specifications.

Results: Observed Failures (%):

		%
Product Visual	Residual Blood/Protein	26
	Residual Contrast Media	50
	Bends/Kinks	26
	Foreign Matter	15
Product Functional:	Guidewire Movement	33
	Shape Conformance	9
	Trackability (1/1)	100
	Balloon Prep (1/1)	100
Packaging:	Seal Fragmentation	63
	Pull Testing	26
	Open Seals	4
	Wrinkling	59
	Mylar Indentations	22

Numerous device failures were observed. These failures included open seals and tears in the product packaging, as well as bends/kinks and the presence of foreign matter (blood and blood components) in several catheter samples.

Functional testing reveled a loss in balloon trackability, balloon prepping difficulties, and excessive friction due to guidewire movement.

Conclusions: Current reprocessed PTA and PTCA catheters lose their original design integrity, and, when reprocessed according to current techniques, are not restored to their original release specifications.

Functional Impairment of a Reprocessed Pulse Oximeter Sensor
David Swedlow, MD

Date: May 6, 1999 (public presentation)*

Objective: To compare a new and reprocessed single use pulse oximeter sensor

Methods: A new and a reused pulse oximeter sensor were visually inspected, then functionally tested in the presence of an EMI noise signal at 4.8 kHz.

Results: Visual Inspection:

Both devices looked nearly identical macroscopically. More careful inspection with a jeweler's loop revealed very slight misalignment of the reprocessed device's detector. X-ray analysis revealed that approximately 2 mm of wire attached to the detector is exposed (not covered by the Faraday shield).

Functional Testing:

New pulse oximeter sensor gave readings of 97 and 98% with the noise generator on.

When the noise generator was turned on, the reprocessed device struggled, missed a few beats and started dropping. Saturation levels were reported down to 48% where the real value was 97%.

Conclusions: Reprocessed single use pulse oximeter sensors can give false high saturation readings leaving the physician with a false sense of assurance which may lead to unrecognized hypoxia and preventable patient injury. Artificially low readings may also occur leading to increased interventions which are not necessary.

* This information was abstracted from a public presentation. It has not been published.

The CHAIRMAN. Thank you very much. The hearing is adjourned.
[Whereupon, at 12:07 p.m., the committee was adjourned.]

○

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